

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

NIPPON SHINYAKU CO., LTD.,)	
Plaintiff,)	
)	C.A. No. 21-1015 (JLH)
v.)	
)	DEMAND FOR JURY TRIAL
SAREPTA THERAPEUTICS, INC.,)	
Defendant.)	
<hr/>		
SAREPTA THERAPEUTICS, INC. and THE)	
UNIVERSITY OF WESTERN AUSTRALIA,)	
Defendant/Counter-Plaintiffs,)	
)	
v.)	
)	
NIPPON SHINYAKU CO., LTD. and NS)	
PHARMA, INC.,)	
Plaintiff/Counter Defendants.)	

EXHIBIT 14B

**NIPPON SHINYAKU CO., LTD. AND NS PHARMA, INC.’S MOTION *IN LIMINE*
NO. 2 TO PRECLUDE IMPROPER ARGUMENT OR EVIDENCE ON UNDISCLOSED
FACTS**

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD.,)	
Plaintiff,)	
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Defendant.)	
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SAREPTA THERAPEUTICS, INC. and THE)	
UNIVERSITY OF WESTERN AUSTRALIA,)	
Defendant/Counter-Plaintiffs,)	
)	
v.)	
)	
NIPPON SHINYAKU CO., LTD. and NS)	
PHARMA, INC.,)	
Plaintiff/Counter Defendants.)	

**NIPPON SHINYAKU CO., LTD. AND NS PHARMA, INC.'S
MOTION *IN LIMINE* NO. 2 TO PRECLUDE
ARGUMENT OR EVIDENCE ON UNDISCLOSED FACTS**

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Christopher J. Betti (admitted *pro hac vice*)
Krista V. Venegas (admitted *pro hac vice*)
Wan-Shon Lo (admitted *pro hac vice*)
Maria E. Doukas (admitted *pro hac vice*)
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*Attorneys for Plaintiff/Counterclaim Defendant
Nippon Shinyaku Co., Ltd. and Counterclaim
Defendant NS Pharma, Inc.*

Dated: April 19, 2024

Nippon Shinyaku and NS Pharma (collectively “NS”) move *in limine* under Fed. R. Evid. 403 and Fed. R. Civ. P. 37(c) to preclude argument and/or evidence from Sarepta and UWA on issues regarding which NS was denied an opportunity to obtain discovery. For each category below, Sarepta and UWA either affirmatively refused to provide the requested information and/or affirmatively confirmed it had no such information through a corporate witness:

A. Accused Product Selection: Sarepta’s corporate witness affirmatively testified [REDACTED] [REDACTED]. Ex. 1, Schnell Dep. at 185:20-186:14. Sarepta’s counsel then, based on privilege, repeatedly instructed the report’s author (a former employee) not to divulge Sarepta’s criteria for selecting VYONDYS 53[®] (golodirsen). Ex. 2, Frank Dep. at 85:18-86:15, 94:5-97:20, 111:4-14.

B. Other Sarepta Exon 53 Research: Sarepta successfully opposed NS’s effort to depose former Sarepta researchers Ryszard Kole and Peter Sazani on their exon 53-related research, and its corporate witness testified that Sarepta lacked knowledge of that research beyond documents. Exs. 3 and 4, Kole and Sazani Motions to Quash; Exs. 5 and 6, Sarepta Objs. to Kole and Sazani Subpoenas;¹ Ex. 1, Schnell Dep. at 107:22-109:12; *see also id.* at 63:11-16, 82:11-84:6, 92:9-93:8, 96:13-97:3, 97:23-98:5.

C. Damages – Licensing Activity: Beyond the text of produced agreements, Sarepta and UWA corporate witnesses affirmatively testified that they had no knowledge of the negotiations [REDACTED]. Ex. 7, Shanahan Dep. at 34:15-35:2, 38:21-25, 57:22-58:8 (UWA witness); Ex. 8, Zenkus Dep. at 88:18-89:17, 90:22-91:3, 91:24-93:2, 112:15-113:5, 116:2-12, 119:8-17, 121:13-24, 122:20-123:8, 123:21-125:3, 153:4-14, 154:2-8, 164:18-165:3 (Sarepta witness). Sarepta’s corporate witness also lacked information regarding

¹ Finnegan Henderson attorneys represent(ed) each of Sarepta, Dr. Kole, and Dr. Sazani.

negotiations of its [REDACTED] licenses. *Id.* at 175:2-13 [REDACTED] royalty rates); *id.* at 197:1-8 (relying upon recitals for “impetus” for [REDACTED] license). Sarepta successfully opposed discovery into its [REDACTED] licenses. D.I. 285.

D. Damages – Alternative Products: Sarepta denied discovery into information regarding products *other* than the accused VYONDYS 53[®], including EXONDYS 51[®] and ELEVIDYS[®] [REDACTED]. D.I. 348; Ex. 9, Jarosz Reb. ¶¶ 44, 130-133, 265; Ex. 10, Forsa Dep. at 99:8-20, 101:4-20 ([REDACTED]); Ex. 11, Wong Dep. at 44:18-48:11 ([REDACTED]).

Under Rule 37, a party failing to disclose information during fact discovery “is not allowed to use that information or witness to supply evidence . . . at a trial” Fed. R. Civ. Pr. 37(c)(1); *Newman v. GHS Osteopathic, Inc., Parkview Hosp. Div.*, 60 F.3d 153, 156 (3d Cir. 1995) (“Rule 37 is written in mandatory terms, and is designed to provide a strong inducement for disclosure of Rule 26(a) material”) (quotations and citation omitted). Courts in this Circuit apply the *Pennypack* factors, *see Konstantopoulos v. Westvaco Corp.*, 112 F.3d 710, 719 (3d Cir. 1997), which all support exclusion here.

Factors 1-3: Admission of Undisclosed Information Would Unfairly Prejudice NS

Allowing Sarepta/UWA to adduce evidence on these issues would unfairly prejudice NS. NS *still* lacks information on these topics. Thus, if Sarepta/UWA adduce new evidence, it would be the height of trial by ambush and incurable. NS will have prepared expert reports, prepared for trial, presented witnesses, and potentially even closed its case-in-chief without such information. NS would be unfairly forced to cross examine adverse witnesses on previously-

unknown information without any preparation. Any remedial measures (*e.g.*, allowing NS to recall witnesses or suspending trial to provide NS an opportunity to adjust) would significantly disrupt the order and efficiency of trial.

Factors 4-6: Sarepta & UWA Cannot Excuse any Eleventh-Hour Disclosure

Each category above (A.-D.) represents either (1) deliberate choices by Sarepta/UWA to oppose certain discovery on proportionality or privilege grounds; and/or (2) affirmative representations that the party lacked information. Sarepta cannot credibly claim that discovery it objected to is now “critical evidence.” And if Sarepta/UWA have, between fact discovery and trial, uncovered previously unknown corporate knowledge responsive to NS’s discovery inquiries, their failure to attempt to supplement and provide fair notice is inexplicable and itself deliberate.

* * *

At bottom, NS should not have to—after diligently inquiring in fact discovery and encountering dead-ends regarding the UWA patents’ licensing history, Sarepta’s exon 53 research and selection of VYONDYS 53[®], and alternative products—wonder whether Sarepta/UWA will offer new explanations at trial. The Court should therefore exclude such evidence.

Eve-of-trial disclosures of new information justifies exclusion under Rule 37, even if that information were central to resolving a case on its merits. *Pharmacyclics LLC v. Cipla Ltd.*, 2020 WL 6581643, at *1 (D. Del. Nov. 10, 2020) (excluding invalidity theory first disclosed two months before trial in pre-trial order exchange). And even if Rule 37 did not justify this information’s exclusion, Rule 403 would. Given Sarepta’s opposition to discovery on these issues and no attempt by Sarepta/UWA to supplement their lack of corporate knowledge, they cannot establish that the probative value of any *still*-undisclosed facts outweighs the unfair prejudice NS would undoubtedly suffer if new facts were adduced.

April 19, 2024

Respectfully submitted,

MORGAN, LEWIS & BOCKIUS LLP

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Defendant Nippon Shinyaku Co., Ltd.
and Counterclaim Defendant NS
Pharma, Inc.*

Exhibit 1 to NS's MIL No. 2

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

-----x
NIPPON SHINYAKU CO., LTD.,

Plaintiff,

-against- C.A. No:
21-1015(GBW)

SAREPTA THERAPEUTICS, INC.,

Defendant.

-----x
SAREPTA THERAPEUTICS, INC. and
THE UNIVERSITY of WESTERN AUSTRALIA
Defendant/Counter-Plaintiffs,

V.

NIPPON SHINYAKU CO. LTD. and
NS PHARMA. INC.,
Plaintiff/Counter-Defendants.
-----x

VIDEOTAPED DEPOSITION of the Defendant,
SAREPTA THERAPEUTICS, INC. by FREDERICK SCHNELL Ph.D.,
taken by the Plaintiff, pursuant to Notice, held at the
law offices of Finnegan, Henderson, Farabow, Garrett &
Dunner, LLP 2 Seaport Lane Boston Massachusetts 02210,
on July 26, 2023, at 9:12 a.m., before a Notary Public
of the State of New York.

[REDACTED]

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1	A P P E A R A N C E S:			1	INDEX		
2	MORGAN, LEWIS & BOCKIUS LLP			2	WITNESS	EXAMINATION BY	PAGE
3	Attorneys for Plaintiff			3	Frederick Schnell	Amanda S. Williamson	6
4	110 North Wacker Drive			4	EXHIBITS		
5	Chicago, Illinois 60606			5	SCHNELL	DESCRIPTION	PAGE
6	BY:	AMANDA S. WILLIAMSON, ESQ.		1		Nippon Shinyaku Co. Ltd. And Ns	8
7		amanda.williamson@morganlewis.com		6		Pharma, Inc.'s Notice of	
8		ALISON P. PATITUCCI, Ph.D.		7		Deposition of Sarepta	
9		alison.patitucci@morganlewis.com		8	2	Therapeutics Pursuant to	
10	FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP					Fed.R.Civ.P.30(B)(6)	
11	Attorneys for Defendant			9	3	Notice to Take Deposition of Dr.	24
12	Two Seaport Lane			10	4	Frank Schnell	
13	Boston, Massachusetts 02210			11	5	Fred Schnell's Declaration	25
14	BY:	ALISSA K. LIPTON, ESQ.		12	6	Dr. Frank Schnell's LinkedIn	49
15		alissa.lipton@finnegan.com				Profile	
16		YOONJIN LEE, ESQ.		13	7	Srpt-Vyds-0227383-407	59
17		yoonjin.lee@finnegan.com		14	8	Provisional Application For	78
18						Patent Cover Sheet 79975	
19	ALSO PRESENT:			15	9	Srpt-Vyds-0227370-78	85
20	GEOFFREY BASSETT-Videographer			16	10	Srpt-Vyds-0227277-314	98
21	AMG Reporting			17	11	Pct Application Number	103
22	MARC EVANS-Inhouse Counsel for Sarepta					Pct/Us2009/061960	
23	JOHN HABERMAN-Inhouse Counsel for Sarepta			18	12	Srpt-Vyds-0214702	130
24				19	13	Srpt-Vyds-0214525	133
25				20	14	Srpt-Vyds-0206708-869	136
				21	15	Srpt-Vyds-0215436-438	147
				22	16	Srpt-Vyds-0213900	153
				23	17	Srpt-Vyds-0214031-32	156
				24	18	Srpt-Vyds-0164361-584	163
				25	19	Srpt-Vyds-0163913-4136	173
						Srpt-Vyds-0201524-588	182
						Srpt-Vyds-0215355-62	192

Page 4				Page 5			
1	20	Srpt-Vyds-0222811-13	196	1	THE VIDEOGRAPHER: Good morning,		
2	21	Srpt-Vyds-0227457-80	202	2	everyone. We are now on the record. Today's		
3	22	Dr. Schnell's Declaration For	206	3	date is July 26, 2023, and the time is 9:12		
4	23	T518/18		4	a.m. Eastern Standard Time. We're here today		
5	24	Srpt-Vyds-0227441-56	208	5	for the videotaped deposition of Dr. Frank		
6	25	Exhibit B Regarding Us Patent	214	6	Schnell in the matter of Nippon Shinyaku Co.,		
7		9,708,361 B2		7	Ltd., versus Sarepta Therapeutics,		
8		Srpt-Vyds-0076874-917	214	8	Incorporated.		
9		Srpt-Vyds-0185379-456	219	9	My name is Jeffrey Bassett. The court		
10	(Exhibits retained by Reporter.)			10	reporter today is Brooke Perry. We are here at		
11				11	2 Seaport Lane in Boston, Massachusetts 02210.		
12				12	At this time, I will ask counsel to		
13				13	please introduce themselves for the record.		
14				14	MS. WILLIAMSON: Good morning. Amanda		
15				15	Williamson here on behalf of Nippon Shinyaku		
16				16	and NS Pharma for Morgan Lewis, and I have with		
17				17	me my colleague, Alison Patitucci.		
18				18	MS. LIPTON: Good morning. Alissa		
19				19	Lipton from Finnegan, LLP, on behalf of Sarepta		
20				20	Therapeutics and University of Western		
21				21	Australia, and with me today is Yoonjin Lee,		
22				22	also from Finnegan, and Mark Evans from		
23				23	Sarepta.		
24				24	THE VIDEOGRAPHER: Thank you.		
25				25	At this time, I will hand it over to		

Page 6

1 the court reporter.
2 FREDERICK SCHNELL, the witness herein,
3 having been first duly sworn by a Notary Public of the
4 State of New York, was examined and testified as
5 follows:
6 THE REPORTER: State your name for the
7 record, please.
8 **THE WITNESS: Frederick Schnell.**
9 THE REPORTER: State your address for
10 the record, please.
11 **THE WITNESS:** [REDACTED]
[REDACTED]
13 EXAMINATION BY
14 MS. WILLIAMSON:
15 Q. Good morning, Dr. Schnell. I think that's more
16 correct. Where are you currently employed?
17 **A. Sarepta Therapeutics.**
18 Q. And what's your title?
19 **A. Director of business development.**
20 Q. And have you been deposed before?
21 **A. This is my first time.**
22 Q. Have you ever testified at a trial or at a
23 hearing?
24 **A. Not that I remember.**
25 Q. And do you understand that you're testifying

Page 8

1 object to some of my questions during the deposition?
2 **A. I do.**
3 Q. And do you understand that, unless she
4 specifically instructs you not to answer, you must
5 continue to answer the question to the best of your
6 ability?
7 **A. I do.**
8 Q. Is there any reason you cannot testify fully
9 and truthfully today?
10 **A. No, there's not.**
11 MS. WILLIAMSON: Let's see. Can I have
12 tab A. Do you have --
13 (Whereupon, Nippon Shinyaku Co. LTD.
14 And NS Pharma, Inc.'s Notice of Deposition of
15 Sarepta Therapeutics Pursuant to
16 FED.R.CIV.P.30(b)(6) was marked as Schnell
17 Exhibit 1, for identification, as of this
18 date.)
19 Q. I'm handing you what's been marked as Exhibit
20 No. 1, entitled Nippon Shinyaku and NS Pharma, Inc.'s,
21 Notice of Deposition of Sarepta Therapeutic's Pursuant
22 to Federal Rule Civil Procedure 30(b)(6).
23 Do you see that?
24 **A. I do.**
25 Q. And are you familiar with this document?

Page 7

1 here under oath today as if you were testifying in
2 court?
3 **A. I do.**
4 Q. My questions and answers will be recorded by
5 the court reporter who is sitting here. So I would just
6 ask that you try to your best to give verbal answers so
7 that she can properly take down the testimony. And,
8 also, I will try not to talk over you if you try not to
9 talk over me; is that fair?
10 **A. That seems fair.**
11 Q. And you'll let me know if you don't understand
12 any question that I'm asking; is that fair?
13 **A. That seems fair.**
14 Q. And if you answer, I'll assume you understood
15 it; is that also fair?
16 **A. That is fair.**
17 Q. If you want to take a break at any time, you
18 can do so. Please just ask and let me know, and I'll
19 let you have a break as soon as there are no pending
20 questions; is that fair?
21 **A. That is fair.**
22 Q. And do you understand that you're required to
23 answer my questions today to the best of your ability?
24 **A. I do.**
25 Q. And do you understand that your counsel may

Page 9

1 **A. I am.**
2 Q. Did you review it in the course of preparing
3 for your deposition?
4 **A. I did.**
5 Q. And do you understand today that you're
6 designated to provide testimony on behalf of Sarepta on
7 certain of the topics contained in this document?
8 **A. I do.**
9 Q. And if you could turn to topics one -- or to
10 Topic 1. That's approximately 10 or so pages into the
11 document. There's a list called Deposition Topics, and
12 if you could read Topic 1.
13 Do you understand that you're designated to
14 provide testimony on Topic Number 1?
15 MS. LIPTON: Subject to our prior
16 responses and objections.
17 **A. I do.**
18 Q. And the same as to Topic Number 2?
19 MS. LIPTON: Also subject to our prior
20 responses and objections.
21 **A. I do.**
22 Q. Topic 3?
23 MS. LIPTON: Subject to our prior
24 responses and objections.
25 **A. I do.**

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[illegible]

Page 64

[illegible]

Page 63

Age Group	Should Take Action (%)	Should Not Take Action (%)
18-29	91	9
30-49	91	9
50-69	91	9
70+	91	9

14 MS. LIPTON: Objection. Outside the
15 scope.

[illegible]

Page 65

[illegible]

24 MS. LIPTON: Objection. Outside the
25 scope.

Page 82

1 [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
6 MS. LIPTON: Objection. Outside the
7 scope and document speaks for itself.
8 [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] Objection. Outside the
18 scope. And once again, I would caution the
19 witness, you may answer but only to the extent
20 you can do so without revealing the substance
21 of any attorney-client communications.
22 [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

[illegible]

Page 83

1 [REDACTED]

3 MS. LIPTON: Objection. Outside the

4 scope.

5 [REDACTED]

12 MS. LIPTON: Objection. Outside the

13 scope.

14 [REDACTED]

18 MS. LIPTON: Objection. Outside the

19 scope.

20 [REDACTED]

25 MS. LIPTON: Objection. Outside the

Page 85

1 [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

15 (Whereupon, SRPT-VYDS-0227370-78 was
16 marked as Schnell Exhibit 7, for
17 identification, as of this date.)
18 Q. Dr. Schnell, I've just handed you what's been
19 marked as Exhibit 7. It's an e-mail bearing the
20 production number SRPT-VYDS-0227370. Do you see that?
21 A. **I do.**
22 Q. Do you recognize this document?
23 A. **I don't.**
24 [REDACTED]
[REDACTED]

Page 90

1 [REDACTED]

6 MS. LIPTON: Objection. Outside the

7 scope.

8 [REDACTED]

13 MS. LIPTON: Objection. Outside the

14 scope. Foundation.

15 [REDACTED]

20 MS. LIPTON: Objection. Outside the

21 scope. Foundation.

22 [REDACTED]

25 MS. LIPTON: Objection. Outside the

Page 92

1 [REDACTED]

14 MS. LIPTON: Objection. Outside the

15 scope. And to the extent it mischaracterizes

16 the document.

17 [REDACTED]

21 MS. LIPTON: Objection. Outside the

22 scope.

23 [REDACTED]

Page 91

1 scope. Foundation.

2 [REDACTED]

17 MS. LIPTON: Objection. Outside the

18 scope. Also vague.

19 [REDACTED]

Page 93

1 [REDACTED]

4 MS. LIPTON: Objection. Outside the

5 scope. Also vague.

6 [REDACTED]

17 MS. LIPTON: Objection. Outside the

18 scope.

19 [REDACTED]

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1 MS. LIPTON: Objection. Outside the
2 scope.
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 (Whereupon, SRPT-VYDS-0227277-314 was
7 marked as Schnell Exhibit 8, for
8 identification, as of this date.)
9 Q. Dr. Schnell, I've handed you what's now been
10 marked as Exhibit No. 7. Do you recognize this
11 document? Oh, 8.
12 A. I do.
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]

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1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]
25 [REDACTED]

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1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]
25 MS. LIPTON: And objection. Vague.

Page 101

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 MS. LIPTON: Objection. Vague.
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]
25 [REDACTED]

1 [REDACTED]

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Bar Index	Approximate Length (Relative)
1	10
2	15
3	90
4	85
5	30
6	40
7	85
8	95
9	90
10	15
11	20
12	85
13	35
14	40
15	40
16	85
17	95
18	95
19	35
20	35
21	80
22	90
23	60
24	90
25	90

Page 107

1 [REDACTED]

2 [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 MS. LIPTON: Objection. Document

8 speaks for it itself.

9 [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 [REDACTED]

20 [REDACTED]

21 [REDACTED]

22 [REDACTED]

23 [REDACTED]

24 [REDACTED]

25 [REDACTED]

26 [REDACTED]

27 [REDACTED]

28 [REDACTED]

29 [REDACTED]

30 [REDACTED]

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1 MS. LIPTON: Objection. Documents
2 speak for themselves.
3 [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
12 MS. LIPTON: Objection. Outside the
13 scope. Calls for speculation.
14 [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
19 MS. LIPTON: Objection. Outside the
20 scope. Calls for speculation.
21 [REDACTED]
[REDACTED]
[REDACTED]
24 MS. LIPTON: Objection. Outside the
25 scope.

[illegible]

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1 [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
7 (Whereupon, SRPT-VYDS-0201524-588 was
8 marked as Schnell Exhibit 18, for
9 identification, as of this date.)
10 MS. WILLIAMSON: Is this 18? Okay.
11 Q. Dr. Schnell, I've handed you what's been marked
12 as Exhibit No. 18.
13 Do you recognize this document?
14 A. I do.
15 [REDACTED]

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[illegible]

Page 184

[illegible]

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Service	Used (%)	Not used (%)
Counseling	85	15
Support groups	80	20
Individual therapy	75	25
Family therapy	70	30
Group therapy	65	35
Online therapy	60	40
Telehealth	55	45
Self-help programs	50	50
Peer support	45	55
Community resources	40	60
Hotlines	35	65
Referrals	30	70
Case management	25	75
Substance abuse treatment	20	80
Mental health services	15	85
Other services	10	90

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[illegible]

10 And I would caution the witness not to
11 reveal such privileged information, but you may
12 answer to the extent you can do so without
13 revealing the substance of privileged
14 information.

15 [REDACTED]

22 [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Page 189

[illegible]

[REDACTED]

[illegible]

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1 time on, that would be great.
2 THE VIDEOGRAPHER: The time is 6:28,
3 and we are off the record.
4 MS. WILLIAMSON: The time on the
5 record, if you could give us a quick
6 calculation.
7 THE VIDEOGRAPHER: We have been on the
8 record for 6 hours and 52 minutes.
9 Thank you, everyone.
10 (Time Noted: 6:28 p.m.)
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1 C E R T I F I C A T E
2 STATE OF NEW YORK)
3) ss.:
4 COUNTY OF QUEENS)
5
6 I, BROOKE E. PERRY, a Notary Public
7 within and for the State of New York, do hereby
8 certify:
9 That FREDERICK SCHNELL Ph.D., the
10 witness whose deposition is hereinbefore set
11 forth, was duly sworn by me and that such
12 deposition is a true record of the testimony
13 given by such witness.
14 I further certify that I am not related
15 to any of the parties to this action by blood
16 or marriage; and that I am in no way interested
17 in the outcome of this matter.
18 IN WITNESS WHEREOF, I have hereunto set
19 my hand this 26th day of July, 2023.
20
21 *Brooke E. Perry*
22 BROOKE E. PERRY
23
24
25

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1 A C K N O W L E D G M E N T
2
3 STATE OF NEW YORK)
4) ss
5
6 COUNTY OF)
7
8 I, FREDERICK SCHNELL Ph.D., hereby certify
9 that I have read the transcript of my testimony taken
10 under oath in my deposition of the 26th day of
11 July, 2023; that the transcript is a true, complete and
12 correct record of my testimony, and that the answers on
13 the record as given by me are true and correct.
14
15 _____
16 FREDERICK SCHNELL Ph.D.
17 Signed and subscribed to before
18 me, this _____ day
19 of _____, 2023.
20
21 _____
22 Notary Public, State of New York
23
24
25

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1 ERRATA SHEET
2 CASE NAME: NIPPON SHINYAKU CO., LTD. V. SAREPTA
3 THERAPEUTICS, INC.
4 DATE OF DEPOSITION: July 26, 2023
5 WITNESS'S NAME: FREDERICK SCHNELL Ph.D.
6 PAGE LINE (S) CHANGE REASON
7 _____|_____|_____|_____
8 _____|_____|_____|_____
9 _____|_____|_____|_____
10 _____|_____|_____|_____
11 _____|_____|_____|_____
12 _____|_____|_____|_____
13 _____|_____|_____|_____
14 _____|_____|_____|_____
15 _____|_____|_____|_____
16 _____|_____|_____|_____
17 _____|_____|_____|_____
18
19
20 FREDERICK SCHNELL Ph.D.
21 SUBSCRIBED AND SWORN TO BEFORE ME
22 THIS ____ DAY OF _____, 20__.
23 _____
24 (NOTARY PUBLIC) MY COMMISSION EXPIRES:
25

Exhibit 2 to NS's MIL No. 2

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD.,)
Plaintiff,)
v.) C.A. NO.: 21-1015 (GBW)
SAREPTA THERAPEUTICS, INC.,)
Defendant.)
_____)

DEPOSITION OF DIANE FRANK, PH.D.

THIS DEPOSITION TAKEN PURSUANT TO NOTICE OF DEPOSITION AT
RICHARDSON WHITMAN LARGE & BADGER, 465 CONGRESS STREET, NINTH
FLOOR, PORTLAND, MAINE, ON FRIDAY, AUGUST 18, 2023, COMMENCING
AT 8:59 A.M.

Page 2		Page 3	
APPEARANCES		STIPULATIONS	
For the Plaintiff:		It is agreed that the deposition shall be taken in the	
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP		first instance in stenotype and when transcribed may be used	
Alissa K. Lipton, Esq.		for all purposes for which depositions are competent under	
Two Seaport Lane		Federal law.	
Boston, Massachusetts 02210-2001		Notice, filing, caption and all other formalities are	
(617) 646-1600		waived. All objections, except as to form, are reserved and	
alissa.lipton@finnegan.com		may be taken in court at time of trial.	
-and-		It is further agreed that if the deposition is not signed	
TAYLOR, MCCORMACK & FRAME, LLC		within thirty (30) days after submission to counsel, the	
Adam S. Taylor, Esq.		signature of the deponent is waived.	
267 Commercial Street			
Portland, Maine 04101			
(207) 828-2005			
ataylor@tmfattorneys.com			
For the Defendant:			
MORGAN, LEWIS & BOCKIUS, LLP			
Alison P. Patitucci, Esq.			
Amanda S. Williamson, Esq.			
110 North Wacker Drive, Suite 2800			
Chicago, Illinois 60601			
(312) 324-1000			
alison.patitucci@morganlewis.com			
amanda.williamson@morganlewis.com			
Also present:			
Bob Giannini, Videographer			
Court reporter:			
Sharon G. Saalfield, LCR No. 147, MA CSR, RDR, CRR			
INDEX		EXHIBITS (Cont'd)	
WITNESS		NUMBER DESCRIPTION	
Diane Frank, Ph.D.		19 11/17/12 Email	
By Ms. Patitucci		20 1/15/13 Email Chain	
EXHIBITS		21 2/26/13 Email with Attachment	
NUMBER DESCRIPTION			
1 Research Report			
2 Subpoena to Diane Frank, with Attachment			
3 Diane Frank's LinkedIn Experience Page			
4 7/11/12 Email Chain			
5 8/27/12 Email Chain			
6 8/20/11 Email Chain			
7 10/04/11 Email Chain with Attachment			
8 1/27/12 Email Chain			
9 7/02/12 Email			
10 8/01/12 Email			
11 8/13/12 Email			
12 8/23/12 Email with Attachment			
13 9/26/12 Email Chain			
14 9/28/12 Email Chain			
15 Sequence ID Spreadsheet			
16 9/28/12 Email Chain			
17 9/28/12 Email Chain			
18 10/29/12 Email			
Errata Sheet:		156	
(Original exhibits were returned to Attorney Patitucci.)			
(Electronic copies of the exhibits are attached to the			
transcript.)			

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1 PROCEEDINGS

2 VIDEOGRAPHER: Good morning. We are on the

3 record. This is the videographer speaking, Bob Giannini.

4 I am with court reporter Sharon Saalfeld with AMG

5 Reporting. Today's date is August 19th (sic), 2023, and

6 the time is 8:59 a.m.

7 We are here in the offices of Richardson,

8 Whitman, Large & Badger, located in Portland, Maine, to

9 take the video deposition of Dr. Diane Frank in the

10 matter of Nippon Shinyaku Company, Ltd, versus Sarepta

11 Therapeutics, Inc.

12 Will counsel please introduce themselves for

13 the record?

14 MS. PATITUCCI: Alison Patitucci from Morgan

15 Lewis representing Nippon Shinyaku. And with me is my

16 colleague, Amanda Williamson.

17 MS. LIPTON: Alissa Lipton from Finnegan on

18 behalf of Sarepta Therapeutics, Diane Frank, and

19 University of Western Australia.

20 MR. TAYLOR: Adam Taylor with Taylor, McCormack

21 & Frank on behalf of Dr. Diane Frank.

22 VIDEOGRAPHER: Thank you. Will the court

23 reporter please swear in the witness?

24 DIANE FRANK,

25 having been duly sworn by Ms. Saalfeld,

Page 8

1 Q. And please allow me to finish asking my question before

2 you begin your answer, and I will wait to ask another

3 question until you are finished answering.

4 A. Of course.

5 Q. Let me know if you don't understand a question, and I'll

6 restate that, okay?

7 A. Absolutely.

8 Q. And can I assume that if you answer my question, you

9 understood it?

10 A. Yes. In general, yeah.

11 Q. If you want to take a break at any time, let me know, and

12 we can do that. I'd just ask that we -- you answer any

13 pending question before we take a break.

14 A. Okay.

15 Q. Do you understand that you're required to answer my

16 questions to the best of your ability?

17 A. Yes.

18 Q. And that your counsel may object to some of my questions,

19 but unless you're instructed not to answer, you must

20 answer my questions.

21 A. Yes.

22 Q. Do you understand that you're required to answer my

23 questions fully and completely?

24 A. Yes.

25 Q. Is there any reason why you cannot testify truthfully and

Page 7

1 was deposed and testified as follows:

2 EXAMINATION

3 BY MS. PATITUCCI:

4 Q. Good morning.

5 A. Hi. Nice to meet you.

6 Q. Can you please state your name and -- your full name and

7 address for the record?

8 A. Diane Elizabeth Frank, [REDACTED]

9 [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 Q. Have you ever been deposed before?

13 A. No.

14 Q. Have you ever testified at a trial or hearing?

15 A. No.

16 Q. Do you understand that you are testifying under oath

17 today as if you were testifying in court?

18 A. Yes.

19 Q. And my questions and your answers will be recorded by the

20 court reporter. Do you understand that?

21 A. Yes.

22 Q. And if I could please ask you to give a verbal answer,

23 because a nod or a shake of the head cannot be recorded;

24 is that fair?

25 A. Yes.

Page 9

1 completely today?

2 A. Not that I'm aware of.

3 Q. Are you feeling sick at all?

4 A. No.

5 [REDACTED]

6 [REDACTED]

7 MS. LIPTON: Just caution the witness you may

8 answer to the extent you can do so without revealing

9 privileged information.

10 [REDACTED]

11 [REDACTED]

12 BY MS. PATITUCCI:

13 [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 [REDACTED]

20 [REDACTED]

21 [REDACTED]

22 [REDACTED]

23 [REDACTED]

24 [REDACTED]

25 [REDACTED]

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Age Group	Gender	Percentage Vaccinated
18-24	Male	~15%
	Female	~15%
25-34	Male	~25%
	Female	~25%
35-44	Male	~35%
	Female	~35%
45-54	Male	~45%
	Female	~45%
55-64	Male	~55%
	Female	~55%
65-74	Male	~65%
	Female	~65%
75-84	Male	~75%
	Female	~75%
85+	Male	~85%
	Female	~85%

[illegible]

Page 85

1

Page 94

1 [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

6 MS. LIPTON: Objection. That calls for
7 privileged information. I'm going to instruct the
8 witness not to answer.
9 [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

14 MS. LIPTON: Same objection. That calls for
15 privileged information. I'm going to instruct the
16 witness not to answer that question.
17 [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

22 MS. LIPTON: Objection. That calls for
23 privileged information. I instruct the witness not to
24 answer that question.
25 [REDACTED]

Page 96

1 MS. LIPTON: Objection. That question calls
2 for privileged information. I instruct the witness not
3 to answer that question.
4 [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

16 MS. LIPTON: And we are asserting that
17 privilege. Do you want to, you know, go off the record
18 and deal with this? I really don't want to waste the
19 witness's time while we have this dispute on the record.
20 MS. WILLIAMSON: We will continue to ask
21 questions on the record and you can continue to make your
22 objections, and we can take it up if we need to after the
23 deposition.
24 MS. LIPTON: Okay. That's fine. I will
25 continue to make my objections to this line of

Page 95

1 [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

9 MS. LIPTON: Objection. That calls for
10 privileged information. I instruct the witness not to
11 answer that question.
12 [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

17 MS. LIPTON: Objection. That calls for
18 privileged information. I instruct the witness not to
19 answer that question.
20 [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Page 97

1 questioning.
2 [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

11 MS. LIPTON: Objection. That question calls
12 for privileged information. I instruct the witness not
13 to answer.
14 [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

19 MS. LIPTON: Objection. Privilege. I instruct
20 the witness not to answer.
21 [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

C E R T I F I C A T E

I, Sharon G. Saalfeld, a Licensed Shorthand Reporter for the State of New Hampshire, Certified Shorthand Reporter for the Commonwealth of Massachusetts, Registered Diplomat Reporter and Certified Realtime Reporter, do hereby certify that the foregoing is a true and accurate transcript of my stenographic notes of the proceeding taken at the place and on the date hereinbefore set forth to the best of my skill and ability under the conditions present at the time.

I further certify that I am neither attorney or counsel for, nor related to or employed by any of the parties to the action in which this proceeding was taken, and further that I am not a relative or employee of any attorney or counsel employed in this case, nor am I financially interested in this action.

Before completion of the deposition, review of the transcript was requested.

The foregoing certification of this transcript does not apply to any reproduction of the same by any means unless under the direct control and/or direction of the certifying reporter.

Sharon Saalfeld

Sharon G. Saalfeld,
Lic. No. 147, CSR, RDR, CRR
Dated: August 20, 2023

Exhibit 3 to NS's MIL No. 2

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF NORTH CAROLINA



NIPPON SHINYAKU CO., LTD.,

Plaintiff,

v.

SAREPTA THERAPEUTICS, INC.,

Defendant.

Case No. 23mc-25

[Pending in the U.S. District Court for
the District of Delaware, C.A. 1:21-
CV-01015]

**NON-PARTY RYSZARD KOLE'S
MOTION TO QUASH SUBPOENAS
OR ALTERNATIVELY FOR A
PROTECTIVE ORDER**

SAREPTA THERAPEUTICS, INC. and
THE UNIVERSITY OF WESTERN
AUSTRALIA,

Defendant/Counter-
Plaintiffs,

v.

NIPPON SHINYAKU CO., LTD.
and NS PHARMA, INC.

Plaintiff/Counter-
Defendants.

Pursuant to Rule 45(d)(3) and 26(b)(2)(C), non-party Ryszard Kole (“Dr. Kole”) hereby moves the Court for an order quashing two subpoenas for documents and testimony issued by Nippon Shinyaku Co., Ltd and NS Pharma, Inc. and dated May 31, 2023 (the “Subpoenas”), or, in the alternative, for a protective order related to the Subpoenas on the grounds that they subject Dr. Kole to an undue burden and seek irrelevant, privileged, burdensome, and/or cumulative discovery in *Nippon Shinyaku Co., Ltd. v. Sarepta Therapeutics, Inc.*, C.A. No. 1:21-cv-1015 (D. Del.).

Pursuant to Local Rule 7.3(a), this Motion is accompanied by a brief which is being filed contemporaneously with this Motion and incorporated by reference herein.

In addition, pursuant to Local Rule 7.3(c), counsel for Dr. Kole believes oral argument is warranted on this Motion because the underlying litigation in Delaware is complex and Dr. Kole believes the Court would benefit from hearing more about his limited connection to the merits of the Delaware litigation.

Pursuant to Local Rule 37.1, counsel for Dr. Kole certifies that after personal consultation and diligent attempts to resolve differences, the parties were unable to reach an accord. In particular, counsel for Dr. Kole and counsel for NS attended a meet and confer on June 29, 2023, where the parties discussed ways to address the third-party subpoenas served on Dr. Kole and other third-party witnesses. The parties could not reach a compromise.

WHEREFORE, Dr. Kole prays the Court for the following relief:

- (a) Enter an Order quashing the Subpoenas in their entirety;
- (b) Alternatively, enter a Protective Order prohibiting Nippon Shinyaku Co., Ltd. And NS Pharma, Inc. from seeking privileged, irrelevant, and/or cumulative information from Dr. Kole and limiting the scope of Dr. Kole's deposition to specific subject matters relevant to the case and to limit the time of the deposition to only that necessary to address such subject matters;

(c) Award Dr. Kole its reasonable attorneys' fees and costs for bringing this Motion; and

(d) Award Dr. Kole such further relief as the Court deems just and proper.

This the 5th day of July, 2023.

BRADLEY ARANT BOULT CUMMINGS, LLP



C. Bailey King, Jr.
North Carolina State Bar No. 34043
Truist Center
214 North Tryon Street, Suite 3700
Charlotte, NC 28202
bking@bradley.com
704-338-6027

Attorney for Non-Party Peter Kole

CERTIFICATE OF SERVICE

I hereby certify that I have this day served the foregoing document by e-mail and by depositing a copy in the United States Mail, first class, postage-prepaid, addressed to the following counsel of record:

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Christopher J Betti
Krista Vink Venegas
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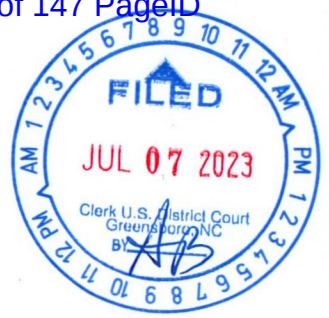
*Of Attorneys for Sarepta Therapeutics, Inc.,
and The University of Western Australia*

This 5th day of July, 2023.



C. Bailey King, Jr.
Attorney for Non-Party Peter Kole

Exhibit 4 to NS's MIL No. 2



UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF NORTH CAROLINA

NIPPON SHINYAKU CO., LTD.,

Plaintiff,

v.

SAREPTA THERAPEUTICS, INC.,

Defendant.

Case No. 23mc26

[Pending in the U.S. District Court for
the District of Delaware, C.A. 1:21-
CV-01015]

**NON-PARTY PETER SAZANI'S
MOTION TO QUASH SUBPOENAS
OR ALTERNATIVELY FOR A
PROTECTIVE ORDER**

SAREPTA THERAPEUTICS, INC. and
THE UNIVERSITY OF WESTERN
AUSTRALIA,

Defendant/Counter-
Plaintiffs,

v.

NIPPON SHINYAKU CO., LTD.
and NS PHARMA, INC.

Plaintiff/Counter-
Defendants.

Pursuant to Rule 45(d)(3) and 26(b)(2)(C), non-party Peter Sazani ("Dr. Sazani") hereby moves the Court for an order quashing two subpoenas for documents and testimony issued by Nippon Shinyaku Co., Ltd and NS Pharma, Inc. and dated May 31, 2023 (the "Subpoenas"), or, in the alternative, for a protective order related to the Subpoenas on the grounds that they subject Dr. Sazani to an undue burden and seek irrelevant, privileged, burdensome, and/or cumulative discovery in *Nippon Shinyaku Co., Ltd. v. Sarepta Therapeutics, Inc.*, C.A. No. 1:21-cv-1015 (D. Del.).

Pursuant to Local Rule 7.3(a), this Motion is accompanied by a brief which is being filed contemporaneously with this Motion and incorporated by reference herein.

In addition, pursuant to Local Rule 7.3(c), counsel for Dr. Sazani thinks oral argument is warranted on this Motion because the underlying litigation in Delaware is complex and Dr. Sazani believes the Court would benefit from hearing more about his limited connection to the merits of the Delaware litigation.

Pursuant to Local Rule 37.1, counsel for Dr. Sazani certifies that after personal consultation and diligent attempts to resolve differences, the parties were unable to reach an accord. In particular, counsel for Dr. Sazani attempted to call Ms. Amanda Williamson, the attorney who signed the subpoenas served on Dr. Sazani on behalf of Nippon Shinyaku Co., Ltd and NS Pharma, Inc., on June 21, 2023 in the early afternoon and left a voicemail informing Ms. Williamson of Dr. Sazani's intent to file this motion to quash. Counsel for Dr. Sazani then followed up with an email re-iterating the statements in the voicemail. Ms. Williamson responded on Friday, June 23, informing Dr. Sazani that NS would oppose this Motion.

WHEREFORE, Dr. Sazani prays the Court for the following relief:

- (a) Enter an Order quashing the Subpoenas in their entirety;
- (b) Alternatively, enter a Protective Order prohibiting Nippon Shinyaku Co., Ltd. And NS Pharma, Inc. from seeking privileged, irrelevant, and/or cumulative information from Dr. Sazani and limiting the scope of Dr. Sazani's deposition to specific

subject matters relevant to the case and to limit the time of the deposition to only that necessary to address such subject matters;

(c) Award Dr. Sazani its reasonable attorneys' fees and costs for bringing this Motion; and

(d) Award Dr. Sazani such further relief as the Court deems just and proper.

This the 6th day of July, 2023.

BRADLEY ARANT BOULT CUMMINGS, LLP



C. Bailey King, Jr.
North Carolina State Bar No. 34043
Truist Center
214 North Tryon Street, Suite 3700
Charlotte, NC 28202
bking@bradley.com
704-338-6027

Attorney for Non-Party Peter Sazani

CERTIFICATE OF SERVICE

I hereby certify that I have this day served the foregoing document by e-mail and by depositing a copy in the United States Mail, first class, postage-prepaid, addressed to the following counsel of record:

Amy M. Dudash
Morgan, Lewis & Bockius LLP
1201 N. Market Street, Suite 2201
Wilmington, DE 19801
Email: amy.dudash@morganlewis.com

Eric Kraeutler
Morgan, Lewis & Bockius LLP
1701 Market Street
Philadelphia, PA 19103
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NS Pharma, Inc., and Nippon Shinyaku Col, Ltd.*

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*Of Attorneys for Sarepta Therapeutics, Inc.,
and The University of Western Australia*

This the 6th day of July, 2023.



C. Bailey King, Jr.

Attorney for Non-Party Peter Sazani

Exhibit 5 to NS's MIL No. 2

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 21-1015 (GBW)
)	
SAREPTA THERAPEUTICS, INC.,)	
)	
Defendant.)	
<hr/>		
SAREPTA THERAPEUTICS, INC. and THE)	
UNIVERSITY OF WESTERN AUSTRALIA,)	
)	
Defendant/Counter-Plaintiffs,)	
)	
v.)	
)	
NIPPON SHINYAKU CO., LTD.)	
and NS PHARMA, INC.)	
)	
Plaintiff/Counter-Defendants.)	

**SAREPTA’S OBJECTIONS TO NS PHARMA’S THIRD-PARTY
SUBPOENAS TO DR. RYSZARD KOLE SEEKING DOCUMENTS
AND THINGS (NOS. 1-3) AND DEPOSITION TESTIMONY**

Pursuant to Rules 26 and 45 of the Federal Rules of Civil Procedure, Sarepta Therapeutics, Inc. (“Sarepta”), through the undersigned counsel, hereby objects and responds to Nippon Shinyaku Co., Ltd. (“Nippon”) and NS Pharma, Inc’s (“NS Pharma”) (collectively, “NS”) Third-Party Subpoena to Dr. Ryszard Kole (“Dr. Kole”) to Produce Documents, Information, or Objects or to Permit Inspection of Premises in a Civil Action (Nos. 1-3) and Third-Party Subpoena to Testify at Deposition.

GENERAL OBJECTIONS

Sarepta makes the following general objections, which are hereby incorporated in their entirety in response to each subpoena generally and each individual request, even if not separately stated therein:

1. Sarepta objects to NS's requests to the extent they seek documents or things or testimony protected by the attorney-client privilege, work-product doctrine, common-interest privilege, and/or any other privilege or immunity, or that are otherwise protected from disclosure. Dr. Kole's inadvertent disclosure of any such documents or things or testimony shall not operate as a waiver of any applicable privilege, doctrine, or immunity.

2. An objection based on attorney-client privilege, work-product immunity, common-interest privilege, and/or any other applicable privilege or immunity should not be construed as a representation that such documents, things, or information exists or existed. Such objections indicate only that the requests are of such scope as to embrace subject matter protected by the attorney-client privilege, work-product immunity, common-interest privilege, and/or any other applicable privilege or immunity. Sarepta does not agree to a waiver of any applicable privilege or immunity, and thus nothing contained in Dr. Kole's responses can be deemed a waiver of any of Sarepta's applicable privilege or immunity.

3. Sarepta objects to NS's requests to the extent they seek to require Dr. Kole to provide documents or information or testimony beyond what is reasonably available to Dr. Kole at present from a reasonable search of files in its possession, custody, or control.

4. Sarepta objects to NS's requests to the extent they seek documents or testimony available through parties to the underlying Delaware litigation.

5. Sarepta objects to NS's requests to the extent they encompass and/or seek "any" and/or "all" documents and things responsive to a request, and/or cover an unlimited time period,

because such requests are overly broad, unduly burdensome, and not proportional to the needs of the case.

6. Sarepta objects to NS's requests to the extent they seek to impose on Dr. Kole requirements, obligations, or duties beyond those of the Federal Rules of Civil Procedure, the Local Rules, any order of this Court.

7. Sarepta incorporates any applicable objections and positions stated in any timely Motion to Quash or Alternatively for a Protective Order Dr. Kole may file in the United States District Court for the Middle District of North Carolina and in any objections Dr. Kole otherwise asserts in response to the subpoenas.

OBJECTIONS TO DEFINITIONS

8. Sarepta objects to NS's definition of "Sarepta" as overly broad, unduly burdensome, not proportional to the needs of the case, and improperly seeking to extend Sarepta's obligations beyond the requirements of the Federal Rules of Civil Procedure to the extent it covers any and all "corporate parents; corporate predecessors (including Antivirals, Inc. and AVI Biopharma, Inc.); corporate affiliates; past or present subsidiaries (directly, indirectly, wholly, or partly owned); joint ventures; divisions; departments; and any present or former officers, directors, managers, general partners, limited partners, principals, shareholders, agents, representatives, and employees of Sarepta Therapeutics, Inc., or any such predecessor in interest, parent, predecessor, affiliate, subsidiary, or joint venture." Any reference to "Sarepta" is understood to exclude discovery from any non-party individuals or affiliate companies.

SPECIFIC OBJECTIONS

REQUEST NO. 1:

A copy of any agreements governing your current or past relationship with Sarepta, including any employment agreements and consulting agreements.

OBJECTIONS

Sarepta incorporates its General Objections here as if set forth in full.

REQUEST NO. 2:

Documents relating to any work you conducted for or on behalf of Sarepta relating to developing and/or testing molecules intended to induce skipping of exon 53 of the dystrophin gene.

OBJECTIONS

Sarepta incorporates its General Objections here as if set forth in full.

REQUEST NO. 3:

Documents relating to any work you conducted for or on behalf of Sarepta relating to golodirsen (also known as Vyondys53®).

OBJECTIONS

Sarepta incorporates its General Objections here as if set forth in full.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Megan E. Dellinger

OF COUNSEL:

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mdellinger@morrisnichols.com

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Sarepta Therapeutics, Inc. and The University of
Western Australia*

CERTIFICATE OF SERVICE

I hereby certify that on June 29, 2023, copies of the foregoing were caused to be served upon the following in the manner indicated:

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Megan E. Dellinger (#5739)

Exhibit 6 to NS's MIL No. 2

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 21-1015 (GBW)
)	
SAREPTA THERAPEUTICS, INC.,)	
)	
Defendant.)	
<hr/>		
SAREPTA THERAPEUTICS, INC. and THE)	
UNIVERSITY OF WESTERN AUSTRALIA,)	
)	
Defendant/Counter-Plaintiffs,)	
)	
v.)	
)	
NIPPON SHINYAKU CO., LTD.)	
and NS PHARMA, INC.)	
)	
Plaintiff/Counter-Defendants.)	

**SAREPTA’S OBJECTIONS TO NS PHARMA’S THIRD-PARTY
SUBPOENAS TO DR. PETER SAZANI SEEKING DOCUMENTS
AND THINGS (NOS. 1-3) AND DEPOSITION TESTIMONY**

Pursuant to Rules 26 and 45 of the Federal Rules of Civil Procedure, Sarepta Therapeutics, Inc. (“Sarepta”), through the undersigned counsel, hereby objects and responds to Nippon Shinyaku Co., Ltd. (“Nippon”) and NS Pharma, Inc.’s (“NS Pharma”) (collectively, “NS”) Third-Party Subpoena to Dr. Peter Sazani (“Dr. Sazani”) to Produce Documents, Information, or Objects or to Permit Inspection of Premises in a Civil Action (Nos. 1-3) and Third-Party Subpoena to Testify at Deposition, both dated May 31, 2023.

GENERAL OBJECTIONS

Sarepta makes the following general objections, which are hereby incorporated in their entirety in response to each subpoena generally and each individual request, even if not separately stated therein:

1. Sarepta objects to NS's requests to the extent they seek documents or things or testimony protected by the attorney-client privilege, work-product doctrine, common-interest privilege, and/or any other privilege or immunity, or that are otherwise protected from disclosure. Dr. Sazani's inadvertent disclosure of any such documents or things or testimony shall not operate as a waiver of any applicable privilege, doctrine, or immunity.

2. An objection based on attorney-client privilege, work-product immunity, common-interest privilege, and/or any other applicable privilege or immunity should not be construed as a representation that such documents, things, or information exists or existed. Such objections indicate only that the requests are of such scope as to embrace subject matter protected by the attorney-client privilege, work-product immunity, common-interest privilege, and/or any other applicable privilege or immunity. Sarepta does not agree to a waiver of any applicable privilege or immunity, and thus nothing contained in Dr. Sazani's responses can be deemed a waiver of any of Sarepta's applicable privilege or immunity.

3. Sarepta objects to NS's requests to the extent they seek to require Dr. Sazani to provide documents or information or testimony beyond what is reasonably available to Dr. Sazani at present from a reasonable search of files in its possession, custody, or control.

4. Sarepta objects to NS's requests to the extent they seek documents or testimony available through parties to the underlying Delaware litigation.

5. Sarepta objects to NS's requests to the extent they encompass and/or seek "any" and/or "all" documents and things responsive to a request, and/or cover an unlimited time period, because such requests are overly broad, unduly burdensome, and not proportional to the needs of the case.

6. Sarepta objects to NS's requests to the extent they seek to impose on Dr. Sazani requirements, obligations, or duties beyond those of the Federal Rules of Civil Procedure, the Local Rules, any order of this Court.

7. Sarepta incorporates any applicable objections and positions stated in any timely Motion to Quash or Alternatively for a Protective Order Dr. Sazani may file in the United States District Court for the Middle District of North Carolina and in any objections Dr. Sazani otherwise asserts in response to the subpoenas.

OBJECTIONS TO DEFINITIONS

8. Sarepta objects to NS's definition of "Sarepta" as overly broad, unduly burdensome, not proportional to the needs of the case, and improperly seeking to extend Sarepta's obligations beyond the requirements of the Federal Rules of Civil Procedure to the extent it covers any and all "corporate parents; corporate predecessors (including Antivirals, Inc. and AVI Biopharma, Inc.); corporate affiliates; past or present subsidiaries (directly, indirectly, wholly, or partly owned); joint ventures; divisions; departments; and any present or former officers, directors, managers, general partners, limited partners, principals, shareholders, agents, representatives, and employees of Sarepta Therapeutics, Inc., or any such predecessor in interest, parent, predecessor, affiliate, subsidiary, or joint venture." Any reference to "Sarepta" is understood to exclude discovery from any non-party individuals or affiliate companies.

SPECIFIC OBJECTIONS

REQUEST NO. 1:

A copy of any agreements governing your current or past relationship with Sarepta, including any employment agreements and consulting agreements.

OBJECTIONS

Sarepta incorporates its General Objections here as if set forth in full.

REQUEST NO. 2:

Documents relating to any work you conducted for or on behalf of Sarepta relating to developing and/or testing molecules intended to induce skipping of exon 53 of the dystrophin gene.

OBJECTIONS

Sarepta incorporates its General Objections here as if set forth in full.

REQUEST NO. 3:

Documents relating to any work you conducted for or on behalf of Sarepta relating to golodirsen (also known as Vyondys53®).

OBJECTIONS

Sarepta incorporates its General Objections here as if set forth in full.

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Sarepta Therapeutics, Inc. and The University of
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June 23, 2023

CERTIFICATE OF SERVICE

I hereby certify that on June 23, 2023, copies of the foregoing were caused to be served upon the following in the manner indicated:

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Megan E. Dellinger (#5739)

Exhibit 7 to NS's MIL No. 2

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

-----x
NIPPON SHINYAKU CO., LTD.,

Plaintiff,

-against- C.A. No:
21-1015(GBW)

SAREPTA THERAPEUTICS, INC.,
Defendant.

-----x
SAREPTA THERAPEUTICS, INC. and
THE UNIVERSITY of WESTERN AUSTRALIA
Defendant/Counter-Plaintiffs,

V.
NIPPON SHINYAKU CO. LTD. and
NS PHARMA. INC.,
Plaintiff/Counter-Defendants.

-----x

VIDEOTAPED DEPOSITION of UNIVERSITY OF WESTERN
AUSTRALIA by PAUL SHANAHAN, taken by the Plaintiff,
pursuant to Notice, held at the law offices of
MinterEllison Level 4, Allendale Square, 77 St Georges
Terrace Perth, Australia 6000, on September 28, 2023, at
8:03 a.m., before a Notary Public of the State of New
York.

Page 2		Page 3	
1	A P P E A R A N C E S:	1	INDEX
2	MORGAN, LEWIS & BOCKIUS LLP	2	WITNESS
3	Attorney for Plaintiff	3	Paul Shanahan
4	110 North Wacker Drive	4	Paul Shanahan
5	Chicago, Illinois 60606	5	
6		6	EXHIBITS
7	BY: Michael T. Sikora, ESQ.	7	DESCRIPTION
8	michael.sikora@morganlewis.com	8	Exhibit 1
9		9	Nippon Shinyaku Co. Ltd. And Ns
10	FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP	10	Pharma, Inc. S. Notice of
11	Attorneys for Defendant	11	Deposition of University of
12	1875 Explorer Street, Suite 800	12	Western Australia Pursuant to
13	Reston, VA 20190-6023	13	Fed. R. Civ. P. 30(B)(6)
14	BY: Ryan P. O'Quinn, Ph.D., ESQ.	14	University of Western
15	ryan.o'quinn@finnegan.com	15	Australia's Intellectual
16		16	Property Policy
17	MINTER ELLISON	17	university of Western
18	Attorneys for Nippon Shinyaku	18	Australia S Responses and
19	Level 4, Allendale Square	19	Objections to Nippon Shinyaku
20	Perth, Australia 6000	20	Co., Ltd. S and Ns Pharma,
21		21	Inc. S Rule 30(B)(6) Notice of
22	BY: JAIMIE WOLBERS, ESQ.	22	Deposition
23		23	Exhibit 4
24		24	Exhibit 5
25		25	Exhibit 6
			Exhibit 7
			Exhibit 8
			Exhibit 9
			Exhibit 10
			Exhibit 11
			Exhibit 12
			Exhibit 13
			Exhibit 14
			Exhibit 15
			Exhibit 16
			Uwa0000015-46
			Uwa0001170-71
			Uwa0001127
			Uwa0001135-36
			Uwa0001145
			Uwa0000051-77
			Us Patent No. 9,994,851 B2
			Srpt-Vyds-0154890-94
			Uwa0001005-08
			Uwa0001023-25
			Uwa0000047-50
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			141
			145

Page 4		Page 5	
1	Exhibit 17	1	P A U L S H A N A H A N, the witness herein, having
2	Chapter 2300 Interference and	2	been first duly sworn by a Notary Public of the State of
3	Derivation Proceedings	3	New York, was examined and testified as follows:
4		4	EXAMINATION BY
5		5	MR. SIKORA:
6		6	Q. State your name for the record, please.
7		7	A. Paul Shanahan.
8		8	Q. State your address for the record, please.
9		9	A. [REDACTED]
10		10	[REDACTED].
11		11	MR. SIKORA: My name is Mike Sikora,
12		12	and I'm an attorney representing Nippon
13		13	Shinyaku and NS Pharma in the litigation case
14		14	number 21-CV-1015 in the U.S. District Court,
15		15	District of Delaware, in front of Judge Gregory
16		16	Williams.
17		17	Counsel for the witness, UWA and
18		18	Sarepta, would you like to make an appearance?
19		19	MR. O'QUINN: My name is Ryan O'Quinn
20		20	from Finnegan representing the University of
21		21	Western Australia, as well as Sarepta.
22		22	BY MR. SIKORA:
23		23	Q. Good morning, Mr. Shanahan. Do you understand
24		24	that this is it a deposition taking place under the laws
25		25	of the United States and the Rules of Federal Civil

Page 34

1 A. Dystrophy, yes.

2 Q. And I think I already committed this sin, but
3 UWA refers to the University of Western Australia as
4 we've been using it today, correct?

5 A. That's correct, yes.

6 Q. So are you prepared to testify regarding
7 topic 52?

8 A. I am.

[illegible]

Page 36

[illegible]

16 MR. O'QUINN: Objection. Vague.

17 Compound.

18 You can answer.

19 [REDACTED]

Page 35

1 [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

6 MR. O'QUINN: I'm going to let you
7 answer this, Mr. Shanahan, but I'll just -- I'm
8 not going to let this go very far, Mike. This
9 isn't within the scope of the topics.

10 You can answer, Mr. Shanahan --

11 THE WITNESS: Thank you.

12 MR. O'QUINN: -- to the extent you
13 don't reveal any privileged information in your
14 response.

15 [REDACTED]

Page 37

[illegible]

8 MR. O'QUINN: Again, I'm going to
9 object to this as outside the scope.

10 You can answer at a high level.

11 THE WITNESS: Sure.

[illegible]

Page 38

1 [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

5 MR. SIKORA: So, Ryan, I just want to
6 -- to the scope objection, I'm asking the
7 witness [REDACTED]
[REDACTED]
[REDACTED]. So I'm not sure how that's outside
10 the scope of any of these.

11 MR. O'QUINN: It's a separate topic
12 that you propounded a discovery on discovery
13 and we've had that conversation with the
14 special master.

15 So like I said, at a high level, I'll
16 allow it, but this is not a deposition about
17 discovery practices.

18 MR. SIKORA: And I'm going to his
19 preparation, so let me just ask another
20 question and make this clearer.
21 [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Page 39

1 [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

14 MR. O'QUINN: You can answer that yes
15 or no if you know, Mr. Shanahan.

16 A. Can you repeat the question.
17 [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

22 MR. SIKORA: Let's do this. If we
23 could have tab J for the witness.

24 THE WITNESS: This first document I
25 looked at, should I mark that 1?

[illegible]

Page 41

1 [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

7 MR. O'QUINN: Objection to form.

8 Foundation.

9 You can answer.

10 [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

22 MR. O'QUINN: Same objection.

23 [REDACTED]

[REDACTED]

[REDACTED]

Page 158

1 cadence Mr. Sikora has requested.
2 THE REPORTER: So --
3 [REDACTED]
4 [REDACTED]
5 (Time Noted: 12:21 p.m.)
6
7
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21
22
23
24
25

Page 160

1 C E R T I F I C A T E
2 STATE OF NEW YORK)
3) ss.:
4 COUNTY OF QUEENS)
5
6 I, BROOKE E. PERRY, a Notary Public
7 within and for the State of New York, do hereby
8 certify:
9 That PAUL SHANAHAN, the witness whose
10 deposition is hereinbefore set forth, was duly
11 sworn by me and that such deposition is a true
12 record of the testimony given by such witness.
13 I further certify that I am not related
14 to any of the parties to this action by blood
15 or marriage; and that I am in no way interested
16 in the outcome of this matter.
17 IN WITNESS WHEREOF, I have hereunto set
18 my hand this 28th day of September, 2023.
19
20 *Brooke E. Perry*
21 BROOKE E. PERRY
22
23
24
25

Page 159

1 A C K N O W L E D G M E N T
2
3 STATE OF NEW YORK)
4) ss
5
6 COUNTY OF)
7
8 I, PAUL SHANAHAN, hereby certify that I
9 have read the transcript of my testimony taken under
10 oath in my deposition of the 28th day of
11 September, 2023; that the transcript is a true, complete
12 and correct record of my testimony, and that the answers
13 on the record as given by me are true and correct.
14
15 _____
16 PAUL SHANAHAN
17 Signed and subscribed to before
18 me, this _____ day
19 of _____, 2023.
20
21 _____
22 Notary Public, State of New York
23
24
25

Page 161

1 ERRATA SHEET
2 CASE NAME: NIPPON SHINYAKU CO., LTD. V. SAREPTA
3 THERAPEUTICS, INC.
4 DATE OF DEPOSITION: September 28, 2023
5 WITNESS'S NAME: PAUL SHANAHAN
6 PAGE LINE (S) CHANGE REASON
7 _____
8 _____
9 _____
10 _____
11 _____
12 _____
13 _____
14 _____
15 _____
16 _____
17 _____
18
19
20 PAUL SHANAHAN
21 SUBSCRIBED AND SWORN TO BEFORE ME
22 THIS _____ DAY OF _____, 20____.
23 _____
24 (NOTARY PUBLIC) MY COMMISSION EXPIRES:
25

Exhibit 8 to NS's MIL No. 2

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

-----x
NIPPON SHINYAKU CO., LTD.,

Plaintiff,

-against-

C.A. No:
21-1015(GBW)

SAREPTA THERAPEUTICS, INC.,

Defendant.

-----x
SAREPTA THERAPEUTICS, INC. and
THE UNIVERSITY of WESTERN AUSTRALIA
Defendant/Counter-Plaintiffs,


V.

NIPPON SHINYAKU CO. LTD. And

NS PHARMA. INC.,

Plaintiff/Counter-Defendants.

-----x
VIDEOTAPED DEPOSITION of the Defendant,
SAREPTA THERAPEUTICS, INC. by JOSEPH ZENKUS, taken by
the Plaintiff, pursuant to Notice, held at the law
offices of Finnegan, Henderson, Farabow, Garrett &
Dunner, LLP 2 Seaport Lane Boston Massachusetts 02210,
on July 25, 2023, at 9:15 a.m., before a Notary Public
of the State of New York.



<p>1 A P P E A R A N C E S: Page 2</p> <p>2 MORGAN, LEWIS & BOCKIUS LLP</p> <p>3 Attorneys for Plain iff/Counter-Defendant</p> <p>4 110 North Wacker Drive</p> <p>5 Chicago, Illinois 60606</p> <p>6</p> <p>7 BY: KRISTA VINK VENEGAS, Ph.D.</p> <p>8 krista.venegas@morganlewis.com</p> <p>9 MICHAEL T. SKIORA, ESQ.</p> <p>10</p> <p>11 FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP</p> <p>12 Attorneys for Defendant/Counter-Plaintiff</p> <p>13 1875 Explorer Street, Suite 800</p> <p>14 Reston, Virginia 20190</p> <p>15 BY: RYAN P. O'QUINN, Ph.D., ESQ.</p> <p>16 ryan.o'quinn@finnegan.com</p> <p>17</p> <p>18 ALSO PRESENT:</p> <p>19 GEOFFREY BASSETT-Videographer</p> <p>20 AMG Reporting</p> <p>21 JESSICA DRISCOLL-Inhouse Counsel for Sarepta</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p>1 INDEX Page 3</p> <p>2 WITNESS EXAM NATION BY page</p> <p>3 Joseph Zenkus Krista Venegas 6</p> <p>4 Joseph Zenkus Ryan O'Quinn 252</p> <p>5</p> <p>6 EXH BITS</p> <p>7 ZENKUS DESCRIPTION page</p> <p>8 1 Notice to Take Deposition of Joe 8</p> <p>9 Zenkus</p> <p>10 2 Nippon Shinyaku Co. Ltd. And 8</p> <p>11 NSPharma, Inc.'s Notice of</p> <p>12 Deposition of Sarepta</p> <p>13 Therapeutics Pursuant to</p> <p>14 Fed.R.Civ.P. 30(B)(6)</p> <p>15 3 Zenkus Deposition Preparation 35</p> <p>16 Binder</p> <p>17 4 SRPT-Vyds-0207178-7237 55</p> <p>18 5 LinkedIn Profile of Joe Zenkus 60</p> <p>19 6 SRPT-Vyds-0154831-862 87</p> <p>20 7 SRPT-Vyds-0154863-889 87</p> <p>21 8 SRPT-Vyds-0154890-94 87</p> <p>22 9 SRPT-Vyds-0207092-177 165</p> <p>23 10 SRPT-Vyds-0207088-91 165</p> <p>24 11 SRPT-Vyds-0206708-869 185</p> <p>25 12 SRPT-Vyds-0206870-933 194</p> <p>13 SRPT-Vyds-0206683-707 195</p> <p>14 Highlights of Prescribing 198</p> <p>15 Information For VYONDYS 53</p> <p>16 15 SRPT-Vyds-0204720-833 207</p> <p>17 16 SRPT-Vyds-0222226-64 216</p> <p>18 17 SRPT-Vyds-0223093-95 223</p>
<p>1 18 SRPT-Vyds-0223092 224</p> <p>2 19 SRPT-Vyds0223211-14 225</p> <p>3 20 Japanese Complaint Filed By 239</p> <p>4 Sarepta Against Nippon Shinyaku</p> <p>5 21 English Excerpt From Exhibit 20 240</p> <p>6 22 [REDACTED] 245</p> <p>7 [REDACTED]</p> <p>8 Sarepta Therapeutics, Inc.'s</p> <p>9 Non-Infringement Contentions</p> <p>10 Exhibit a-1 246</p> <p>11</p> <p>12 (Exhibits retained by Reporter.)</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p>1 THE VIDEOGRAPHER: Good morning, Page 5</p> <p>2 everyone. Today's date is July 25, 2023, and</p> <p>3 the time is 9:15 a.m. Eastern Standard Time,</p> <p>4 and we are on the record. You're here today</p> <p>5 for the video-recorded deposition of Joe Zenkus</p> <p>6 in the matter of Nippon Shinyaku Co., LT --</p> <p>7 Limited vs. Sarepta Therapeutics, Incorporated.</p> <p>8 Is that correct?</p> <p>9 My name is Geoffrey Bassett with AMG</p> <p>10 Reporting. And the court reporter today is</p> <p>11 Brooke Perry. At this time, I will ask counsel</p> <p>12 to introduce themselves for the record.</p> <p>13 MS. VENEGAS: Krista Venegas with</p> <p>14 Morgan Lewis on behalf of Nippon Shinyaku and</p> <p>15 NS Pharma.</p> <p>16 MR. O'QUINN: Ryan O'Quinn with</p> <p>17 Finnegan on behalf of Sarepta Therapeutics, the</p> <p>18 University of Western Australia, and the</p> <p>19 witness.</p> <p>20 THE VIDEOGRAPHER: All right. At this</p> <p>21 time, I will hand it over to the court</p> <p>22 reporter.</p> <p>23 J O S E P H Z E N K U S, the witness herein, having been</p> <p>24 first duly sworn by a Notary Public of the State of New</p> <p>25 York, was examined and testified as follows:</p>

Page 86

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 MR. O'QUINN: Outside the scope.
15 You can answer if it you know in your
16 personal capacity.
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]
25 [REDACTED]

Page 88

1 marked as Exhibit 8, for identification, as of
2 this date.)
3 THE VIDEOGRAPHER: The time is now
4 12:35. We are on the record.
5 BY MS. VENEGAS:
6 Q. Welcome back from lunch.
7 A. Thank you.
8 Q. We're going to turn to talking about some of
9 the agreements that are in Exhibit 3; however, I'm going
10 to pass you individual exhibits.
11 A. Okay. So do you want me to use those instead
12 of the binder, or it doesn't matter?
13 Q. They should be identical copies, but if for
14 some reason you need still to refer to Exhibit 3, you're
15 welcome to do so, if that gives you comfort or.
16 A. No, it doesn't matter as long as I have the
17 agreement.
18 MS. VENEGAS: I'm going to go ahead and
19 introduce Exhibit 6, which is titled [REDACTED]
20 [REDACTED], and it's Bates number starts
21 at SRPT-VYDS-0154831.
22 And maybe Mike can pass these across
23 the table as I go.
24 And I'm going to introduce Exhibit 7,
25 which is titled [REDACTED]

Page 87

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 (Reporter Clarification.)
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 MR. O'QUINN: We've been on about an
13 hour, Counsel. Is it time for a break?
14 MS. VENEGAS: Sure. That's fine.
15 THE VIDEOGRAPHER: The time is 11:44.
16 We're off the record.
17 (Whereupon, a luncheon recess was taken
18 from 11:45 a.m. to 12:35 p.m.)
19 (Whereupon, SRPT-VYDS-0154831-862 was
20 marked as Exhibit 6, for identification, as of
21 this date.)
22 (Whereupon, SRPT-VYDS-0154863-889 was
23 marked as Exhibit 7, for identification, as of
24 this date.)
25 (Whereupon, SRPT-VYDS-0154890-94 was

Page 89

1 [REDACTED] beginning Bates Number
2 SRPT-VYDS-0154863.
3 And Exhibit 8 titled [REDACTED]
4 [REDACTED] beginning Bates Number
5 SRPT-VYDS-0154890.
6 And I'll go ahead and hand these to the
7 witness.
8 A. Thanks.
9 Q. And let's start with Exhibit 6. Can you
10 confirm for me that exhibit is also one of the documents
11 that is in Exhibit 3, correct?
12 A. Yes.
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]
25 [REDACTED]

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 MR. O'QUINN: Objection to the extent
10 it seeks a legal conclusion.
11 You can answer.
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]
25 [REDACTED]

Page 92

1 MR. O'QUINN: Objection to form.
2 Vague.
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 MR. O'QUINN: Same objection.
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 MR. O'QUINN: You can answer that
13 question, Mr. Zenkus, to the extent you don't
14 reveal privileged information.
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]
25 [REDACTED]

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]
25 [REDACTED]

Page 93

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 MR. O'QUINN: Object to form.
22 Compound.
23 [REDACTED]
24 [REDACTED]
25 [REDACTED]

Page 110

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]

15 MR. O'QUINN: Objection to form. Calls
16 for speculation.
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]

24 MR. O'QUINN: Objection to form, to the
25 extent it calls for expert testimony.

Page 112

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]

17 MR. O'QUINN: Objection to the extent
18 it calls for legal conclusion, calls for
19 speculation.
20 You can answer.
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]
25 [REDACTED]

Page 111

1 You can answer to the extent you don't
2 reveal privileged or third-party confidential
3 information.
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]

15 MR. O'QUINN: Objection to the extent
16 it seeks expert testimony.
17 You can answer, if you can do so,
18 without revealing privileged or third-party
19 confidential information.
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]
25 [REDACTED]

Page 113

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]

12 MR. O'QUINN: Objection to the extent
13 it seeks a legal conclusion.
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]

23 MR. O'QUINN: Objection to the extent
24 it misrepresents the document.
25 You can testify.

Page 114

1 A. Can you repeat the question?
2 Q. Sure.
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]
25 [REDACTED]

Page 116

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 MR. O'QUINN: Objection to form, to the
8 extent it calls for speculation.
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]
25 [REDACTED]

Page 115

1 MR. O'QUINN: Objection to the extent
2 it seeks a legal conclusion.
3 You can answer.
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]
25 [REDACTED]

Page 117

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 MR. O'QUINN: Objection to the extent
8 it calls for speculation.
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 MR. O'QUINN: You can answer that to
18 the extent you don't disclose any privileged
19 information.
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]
25 [REDACTED]

Page 118

1 MR. O'QUINN: You can answer that yes
2 or no Mr. Zenkus.
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 MR. O'QUINN: You can answer that yes
10 or no.
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 MR. O'QUINN: You can answer that yes
17 or no.
18 [REDACTED]
19 MR. O'QUINN: Please let me get my
20 objections on the record.
21 THE WITNESS: Sorry.
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]
25 [REDACTED]

Page 120

1 [REDACTED]
2 MR. O'QUINN: You can answer that yes
3 or no, Mr. Zenkus.
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 MR. O'QUINN: Objection to the extent
19 it misrepresents the document, but you can
20 answer.
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]
25 [REDACTED]

Page 119

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 MR. O'QUINN: Please don't disclose any
12 privileged information in your response, but
13 you can answer.
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 MR. O'QUINN: Calls for speculation.
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]
25 [REDACTED]

Page 121

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 MR. O'QUINN: You can answer that
16 question, Mr. Zenkus, if it you can do so
17 without revealing privileged information.
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]
25 [REDACTED]

Page 122

1 [REDACTED]
2 [REDACTED]
3 MR. O'QUINN: Objection to the extent
4 it seeks a legal conclusion, but you can
5 answer.

6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]

22 MR. O'QUINN: You can answer that if
23 you can do so without revealing privileged
24 information.

25 [REDACTED]

Page 124

1 [REDACTED]
2 MR. O'QUINN: Objection. Calls for
3 speculation. You can answer.

4 [REDACTED]
5 [REDACTED]
6 [REDACTED]

7 MS. VENEGAS: As to the objections, I'm
8 entitled to the witness's corporate answer if
9 he has one, before you object to speculation.
10 So if he says the corporation doesn't know and
11 he doesn't know, that seems like an appropriate
12 objection.

13 MR. O'QUINN: You're welcome to
14 question him in that fashion. I'm going to
15 make my objections for the record.

16 MS. VENEGAS: Well, that's what I asked
17 him.

18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]

23 MR. O'QUINN: Objection to the extent
24 it calls for speculation.

25 [REDACTED]

Page 123

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]

17 MR. O'QUINN: Objection to the extent
18 it misrepresents the document.

19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]
25 [REDACTED]

Page 125

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]

18 MR. O'QUINN: Outside the scope. You
19 can answer if you know, to the extent it seeks
20 expert testimony.

21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]
25 [REDACTED]

Page 150

1 [REDACTED]

2 MR. O'QUINN: Same objection.

3 [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 [REDACTED]

10 [REDACTED]

11 MR. O'QUINN: Objection to form,

12 foundation.

13 [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 [REDACTED]

20 [REDACTED]

21 [REDACTED]

22 [REDACTED]

23 [REDACTED]

24 [REDACTED]

25 [REDACTED]

Page 152

1 [REDACTED]

2 [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 MR. O'QUINN: You can answer to the

20 extent you don't reveal privileged information,

21 Mr. Zenkus.

22 [REDACTED]

23 [REDACTED]

24 [REDACTED]

25 [REDACTED]

Page 151

1 [REDACTED]

2 [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 [REDACTED]

20 [REDACTED]

21 [REDACTED]

22 [REDACTED]

23 [REDACTED]

24 [REDACTED]

25 [REDACTED]

Page 153

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11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 MR. O'QUINN: You can answer yes or no,

20 Mr. Zenkus.

21 [REDACTED]

22 [REDACTED]

23 [REDACTED]

24 [REDACTED]

25 [REDACTED]

Page 154

1 [REDACTED]
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14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 MR. O'QUINN: You can answer that yes
22 or no, Mr. Zenkus.
23 [REDACTED]
24 [REDACTED]
25 [REDACTED]

Page 156

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
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9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 MR. O'QUINN: Objection. Vague.
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]
25 [REDACTED]

Page 157

1 [REDACTED]
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10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
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23 [REDACTED]
24 [REDACTED]
25 [REDACTED]

Page 162

1 [REDACTED]
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5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 MS. VENEGAS: And I apologize, Madam
13 Court Reporter.
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 MR. O'QUINN: You can answer that yes
24 or no, Mr. Zenkus.
25 [REDACTED]

Page 164

1 [REDACTED]
2 [REDACTED]
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25 [REDACTED]

Page 163

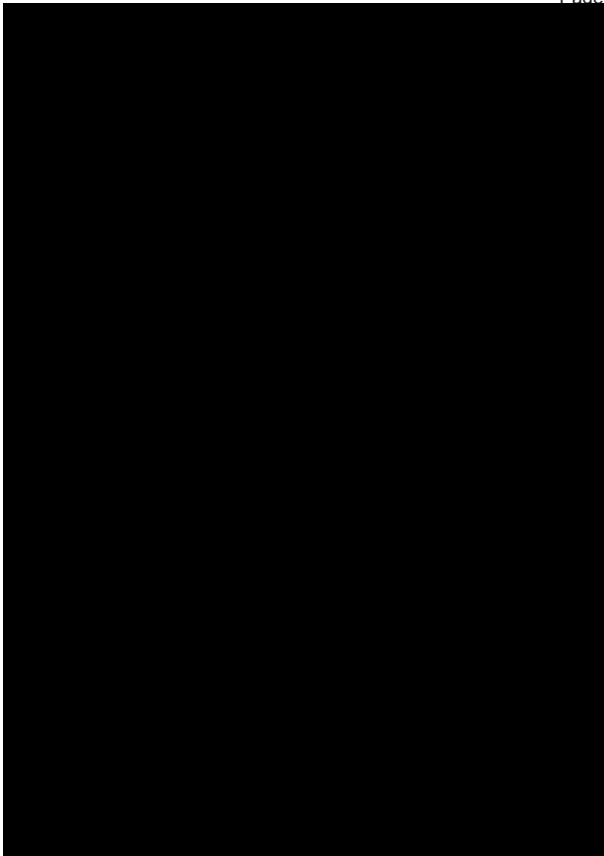
1 [REDACTED]
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8 [REDACTED]
9 [REDACTED]
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11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 MR. O'QUINN: You can answer that yes
15 or no, Mr. Zenkus.
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
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24 [REDACTED]
25 [REDACTED]

Page 165

1 [REDACTED]
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6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 MS. VENEGAS: I'm going to mark some
11 more exhibits; J, K, and L.
12 (Whereupon, SRPT-VYDS-0207092-177 was
13 marked as Exhibit 9, for identification, as of
14 this date.)
15 (Whereupon, SRPT-VYDS-0207088-91 was
16 marked as Exhibit 10, for identification, as of
17 this date.)
18 MS. VENEGAS: Okay. Let's mark as
19 Exhibit 9, a document entitled License
20 Agreement, Bates number SRPT-SVYDS-0207092.
21 We'll mark as Exhibit 10, a document
22 entitled Amendment Number 1 to License
23 Agreement, Bates number starting
24 SRPT-VYDS-0207088.
25 And we'll start with these at the

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1 A. Yes.
2 THE VIDEOGRAPHER: Sorry, Mr. Zenkus,
3 do you mind scooting a little bit to your
4 right?
5 THE WITNESS: Sorry. This way you mean
6 (indicating)?
7 THE VIDEOGRAPHER: Yes.
8
9
10
11
12
13
14 MR. O'QUINN: Objection to the extent
15 it seeks a legal conclusion and to the extent
16 it misrepresents the document.
17 You can answer.
18
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Page 177

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5 And please don't reveal any privileged
6 information in your response.
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1 MS. VENEGAS: I'm going to go ahead and
2 mark as the next exhibit in order, which I
3 believe is 12, a document entitled Consortium
4 Agreement beginning Bates page
5 SRPT-VYDS-0206870.
6 (Whereupon, SRPT-VYDS-0206870-933 was
7 marked as Exhibit 12, for identification, as of
8 this date.)
9 BY MS. VENEGAS:
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]
25 [REDACTED]

Page 196

1 [REDACTED]
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3 [REDACTED]
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16 [REDACTED]
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24 [REDACTED]
25 [REDACTED]

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12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 MS. VENEGAS: Mark next in order
19 Exhibit No. 13, which is entitled Nonexclusive
20 License Agreement Beginning Bates number
21 SRPT-VYDS-0206683.
22 (Whereupon, SRPT-VYDS-0206683-707 was
23 marked as Exhibit 13, for identification, as of
24 this date.)
25 Q. Mr. Zenkus, I believe you also mentioned

Page 197

1 [REDACTED]
2 [REDACTED]
3 MR. O'QUINN: Objection. Vague.
4 You can answer.
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 (Reporter Clarification.)
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
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23 [REDACTED]
24 [REDACTED]
25 [REDACTED]

Page 254

1 [REDACTED]
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9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED]
19 MR. O'QUINN: I pass the witness.
20 MS. VENEGAS: No further questions.
21 THE VIDEOGRAPHER: All right. The time
22 is now 6:35 p.m., and we are off the record.
23 Thank you, everyone.
24 (Time Noted: 6:36 p.m.)
25

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1 C E R T I F I C A T E
2 S T A T E O F N E W Y O R K)
3) s s .:
4 C O U N T Y O F Q U E E N S)
5
6 I, BROOKE E. PERRY, a Notary Public
7 within and for the State of New York, do hereby
8 certify:
9 That JOSEPH ZENKUS, he witness whose
10 deposition is hereinbefore set forth, was duly
11 sworn by me and that such deposition is a true
12 record of the testimony given by such witness.
13 I further certify that I am not related
14 to any of the parties to this action by blood
15 or marriage; and that I am in no way interested
16 in the outcome of this matter.
17 IN WITNESS WHEREOF, I have hereunto set
18 my hand this 25 h day of July, 2023.
19
20
21 -----
22 BROOKE E. PERRY
23
24
25

Page 255

1 A C K N O W L E D G M E N T
2
3 S T A T E O F N E W Y O R K)
4 :ss
5 C O U N T Y O F)
6
7 I, JOSEPH ZENKUS, hereby certify that I
8 have read the transcript of my testimony taken under
9 oath in my deposition of the 25th day of July, 2023;
10 that the transcript is a true, complete and correct
11 record of my testimony, and hat the answers on the
12 record as given by me are true and correct.
13
14 _____
15 JOSEPH ZENKUS
16
17 Signed and subscribed to before
18 me, this day
19 of , 2023.
20
21 _____
22 Notary Public, State of New York
23
24
25

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1 E R R A T A S H E E T
2 C A S E N A M E : N I P P O N S H I N Y A K U C O . , L T D . V . S A R E P T A
3 T H E R A P E U T I C S , I N C .
4 D A T E O F D E P O S I T I O N : J u l y 2 5 , 2 0 2 3
5 W I T N E S S ' S N A M E : J O S E P H Z E N K U S
6 P a g e L I N E (S) C H A N G E R E A S O N
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20 J O S E P H Z E N K U S
21 S U B S C R I B E D A N D S W O R N T O B E F O R E M E
22 T H I S _ _ _ D A Y O F _ _ _ , 2 0 _ .
23 _ _ _ _ _
24 (N O T A R Y P U B L I C) M Y C O M M I S S I O N E X P I R E S : --
25

Exhibit 9 to NS's MIL No. 2

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

NIPPON SHINYAKU CO., LTD.,

Plaintiff,

v.

SAREPTA THERAPEUTICS, INC.,

Defendant.

C.A. No. 21-1015-GBW

SAREPTA THERAPEUTICS, INC. and THE
UNIVERSITY OF WESTERN AUSTRALIA,

Defendant/Counter-Plaintiffs,

v.

NIPPON SHINYAKU CO., LTD. and NS
PHARMA, INC.

Plaintiff/Counter-Defendants.

REBUTTAL EXPERT REPORT OF JOHN C. JAROSZ

October 11, 2023

[REDACTED]

43. Solid Biosciences is also developing a DMD gene therapy product, known as SGT-001.⁸⁵ The therapy is currently undergoing Phase I/II clinical trials, with an estimated primary completion date of December 2026.⁸⁶

44. Sarepta expects that the entrance of gene therapy treatments for DMD, specifically ELEVIDYS®, will impact future sales of exon-skipping therapies. In its 2022 10-K, Sarepta wrote that “development and commercialization of our gene therapy product candidates, such as SRP-9001, may compete with or supersede our current approved products, which may impact future revenues from sales of our current approved products.”⁸⁷ When asked about the impact of the potential launch of ELEVIDYS® on sales of Sarepta’s exon-skipping products, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Analyst reports, in fact, have confirmed that the entry of gene therapy is expected to negatively impact sales of exon-skipping DMD products. For example, an August 2023 report by Needham “assume[d] that the prevalent population [for Sarepta’s PMO products] will decrease over time if gene therapies (Elevidys) become approved for DMD.”⁸⁹

⁸⁵ <https://muscular dystrophy news.com/sgt-001/> (viewed August 18, 2023).

⁸⁶ <https://clinicaltrials.gov/study/NCT03368742?intr=SGT-001&rank=1> (viewed August 18, 2023); <https://www.solidbio.com/about/media/press-releases/solid-biosciences-presents-new-sgt-001-ignite-dmd-study-results-at-world-muscle-society-2022-congress-demonstrating-improvements-in-ambulatory-function> (viewed August 18, 2023).

⁸⁷ Sarepta 10-K 2022, at p. 40.

⁸⁸ [REDACTED]

⁸⁹ Needham, “2Q:23 Update; 1st Patient Dosed with Elevidys; EMBARK Readout Remains Critical,” August 3, 2023, at p. 3.

[REDACTED]

more vials than it actually did in 2021.²⁴⁸ Based on conversations with NS Japan personnel, Mr. Hosfield assumed NS Japan and NS Pharma would have had the capacity to achieve such sales,²⁴⁹ but as a matter of economics, it is likely such a dramatic increase in sales would have had some impact on NS Japan or NS Pharma’s supply chain. Mr. Hosfield has provided no documentary proof of either company’s ability to expand its production to such but-for levels.

130. Mr. Hosfield also did nothing to account for the existence of EXONDYS 51[®]. Mr. Hosfield acknowledged that “patients with an exon 52 deletion or mutation can be treated with VILTEPSO, VYONDYS 53, or EXONDYS 51” and that, therefore, “for this group of patients, EXONDYS 51 is a potential acceptable non-infringing substitute.”²⁵⁰ Mr. Hosfield further acknowledged that according to testimony from Gardner Gendron, NS Pharma’s Vice President of Commercial, “[REDACTED] of exon 53 amenable patients would be potential patients for either VILTEPSO or EXONDYS 51 (if [VYONDYS] 53 were not on the market).”²⁵¹ Nevertheless, Mr. Hosfield proceeded to assume that *all* VYONDYS 53[®] units would be captured by VILTEPSO[®] and *none* would be captured by EXONDYS 51[®].

131. To support his assumption, Mr. Hosfield argued that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

²⁴⁸ Calculated as [REDACTED] but-for units / [REDACTED] actual units and [REDACTED] but-for units / [REDACTED] actual units. [REDACTED] but-for units from Hosfield Report, at p. 108; [REDACTED] actual units from Rebuttal Tab 37.

²⁴⁹ Hosfield Report, at pp. 67-69.

²⁵⁰ Hosfield Report, at p. 64.

²⁵¹ Hosfield Report, at p. 65.

²⁵² Hosfield Report, at p. 78.

[REDACTED] While these justifications may explain why *some* VYONDYS 53[®] units would not be captured by EXONDYS 51[®], Mr. Hosfield has failed to adequately justify his assumption that *none* would be captured by EXONDYS 51[®], especially if this were the only route for Sarepta to treat patients with a therapy that can treat exon 52 deletions.

132. In fact, I understand from Mr. Dan Madden, Vice President of Patient Services at Sarepta, that Sarepta produced a document that, as of March 10, 2023, [REDACTED]
[REDACTED]
Specifically, as of March 10, 2023, [REDACTED]
[REDACTED] Mr. Hosfield reviewed this document but presumably chose to ignore it.²⁵⁶ Mr. Hosfield [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED].

133. I understand from Dr. Nelson that patients amenable to both therapies are not necessarily choosing only based on the specific exon to be skipped but also based on other factors as well, such as the perceived expected benefits from the therapy.²⁵⁷ In fact, I understand that physicians and patients exhibit loyalty to the Sarepta brand,²⁵⁸ while a weakness of NS Pharma

²⁵³ Hosfield Report, at pp. 65-66. *See also* Gendron Deposition, at 205:21-25. Contrary to Mr. Hosfield's assumptions, Sarepta marketing documents show that EXONDYS 51[®] and VYONDYS 53[®] were advertised together, with a specific callout that "[p]atients with DMD who have a deletion of exon 52 may be treated with a therapy that skips either exon 51 or exon 53." SRPT-VYDS-0212478-479, at 478.

²⁵⁴ Conversation with Mr. Dan Madden, October 5, 2023; [REDACTED]

²⁵⁵ [REDACTED]
²⁵⁶ Hosfield Report, at Exhibit 2, p. 7.

²⁵⁷ Conversation with Dr. Nelson, October 2, 2023.

²⁵⁸ According to Mr. Sudovar, there is resistance in adoption of VILTEPSO[®] among physicians and patients due to brand loyalty to Sarepta products. Sudovar Deposition, at 21:21-22:5.

has been its low recognition and lack of established presence or history in the DMD therapy marketplace.²⁵⁹

d. Conclusion

134. Adjusting for only a subset of flaws in Mr. Hosfield's analysis related to the calculation of lost units reduces his claimed lost vial sales from [REDACTED], and his Scenario 1 lost profits by [REDACTED] percent, from \$[REDACTED] million to \$[REDACTED] million.²⁶⁰ While difficult to quantify, the lost vials are likely significantly lower than this since, as described above, there are many additional factors that would reduce lost units even further that Mr. Hosfield did not address in his analysis.

2. NS Japan's Lost Profits

135. As described above, there were two components of Mr. Hosfield's calculation of NS Japan's lost profits associated with the claimed lost units: 1) lost profits related to the lost revenues that it would have otherwise earned from the supply price paid by NS Pharma ("NS Japan direct lost profits") and 2) lost profits that it would have otherwise received from NS Pharma resulting from NS Pharma's additional sales of VILTEPSO® ("NS Japan indirect lost profits").²⁶¹

136. However, Mr. Hosfield overstated the profits that NS Japan would have achieved on each lost unit for several reasons.

- He incorrectly calculated NS Pharma's average net selling price.

²⁵⁹ NS00073341-368, at 354.

²⁶⁰ Rebuttal Tab 6; Rebuttal Tab 8. [REDACTED] million. For this adjustment, I only excluded free units and accounted for the natural ramp up, as described above.

²⁶¹ Hosfield Report, at pp. 79-80.

[REDACTED]

263. Economic costs include those associated with the marketplace frictions that may arise in transitioning to the non-infringing, next best alternative.⁵¹³ To the extent that the transition to a non-infringing alternative involves some delay, the accused infringer may, for example, be unable to sell its product during the period in which the non-infringing alternative is developed, or it may suffer impairment of existing customer relationships or consumer goodwill. Further, to the extent that the non-infringing and infringing products are imperfect substitutes, the accused infringer may experience lower sales volumes or prices for its non-infringing products, and others.⁵¹⁴ These costs should, to the extent possible, be considered when analyzing Design-Around costs.

264. In the present case, I am not aware of any evidence suggesting that Sarepta has or had (as of December 2019) any viable design-around alternatives that would impose a limit on the amount that it should be willing to pay for access to the NS Patents-in-Suit.

265. [REDACTED]

[REDACTED]

[REDACTED] Likewise, [REDACTED]

⁵¹³ Seaman, Christopher B., “Reconsidering the Georgia-Pacific Standard for Reasonable Royalty Patent Damages,” *BYU Law Review*, Issue 5, Article 5 (2010): 1661-1728, at 1718-1721.

⁵¹⁴ Seaman, Christopher B., “Reconsidering the Georgia-Pacific Standard for Reasonable Royalty Patent Damages,” *BYU Law Review*, Issue 5, Article 5 (2010): 1661-1728, at 1716-1717 (“A common refrain is that ‘[a] product lacking the advantages of that patented can hardly be termed a substitute ‘acceptable’ to the customer who wants those advantages.’ The latter definition of an ‘acceptable’ substitute is likely too narrow to be useful, because unpatented substitutes often do not have the exact attributes or qualities as validly patented inventions. Rather, ‘[i]n real markets for actual products, substitution is a matter of degree’ because ‘[s]ome, but not all, customers will substitute a product without the patented technology for one with the technology.’ . . . As Judge Easterbrook has explained, ‘competition is not an all-or-none process. There are degrees of substitutability.’ Thus, the value of ‘[p]atented items in an imperfect . . . market will be restrained . . . depending on the degree to which substitutes are functionally equivalent.’ . . . ‘[P]roduct substitution is a matter of degree and occurs across a spectrum.’” (internal citations omitted)).

⁵¹⁵ <https://www.sarepta.com/srp-5053> (viewed July 26, 2023).

⁵¹⁶ [REDACTED]

While ELEVIDYS® and [REDACTED] are both non-infringing alternatives available to most patients amenable to exon 53 skipping, neither product was commercialized and available for use during the damages period in this case. Therefore, I do not consider them for my analysis here. However, I reserve the right to update my analysis ahead of trial in light of new evidence and data.

4. Summary of Quantitative Analysis

266. For allegedly infringing Sarepta products, perhaps the most reliable quantitative indicator of a reasonable royalty for the NS Patents-in-Suit is from the Licensing Comparables Approach. As discussed above, neither the Incremental Benefits Approach nor the Design-Around Cost approach are very informative in this case, though the former suggests a very modest royalty payment, at best.

267. The Licensing Comparables Approach suggests a royalty rate in the range of [REDACTED] percent to [REDACTED] percent of net sales in the U.S. and [REDACTED] percent to [REDACTED] percent of net sales outside of the U.S. based on NS Japan's and Sarepta's licenses for exon skipping products.⁵¹⁸ Applied to \$[REDACTED] million in U.S. Accused Sales through March 31, 2023, a [REDACTED] percent royalty range would suggest reasonable royalties of approximately \$[REDACTED] million to \$[REDACTED] million.⁵¹⁹ Applied to \$[REDACTED] million in O.U.S. Accused Sales through March 31, 2023, a [REDACTED] percent royalty range would suggest reasonable royalties of approximately \$[REDACTED] to \$[REDACTED] million.⁵²⁰

⁵¹⁷ See, e.g., SRPT-VYDS-0210800, at tab 'DMD US Total.'

⁵¹⁸ See Section V.B.1.c.

⁵¹⁹ Calculated as \$[REDACTED] = \$[REDACTED] × [REDACTED] percent; \$[REDACTED] million = \$[REDACTED] × [REDACTED] percent. \$[REDACTED] million in U.S. net sales from Rebuttal Tab 38.

⁵²⁰ Calculated as \$[REDACTED] × [REDACTED] percent; \$[REDACTED] million = \$[REDACTED] × [REDACTED] percent. \$[REDACTED] million in O.U.S. net sales from Rebuttal Tab 39.

CERTIFICATE OF SERVICE

I hereby certify that on October 11, 2023, copies of the foregoing were caused to be served upon the following in the manner indicated:

Amy M. Dudash, Esquire
MORGAN, LEWIS & BOCKIUS LLP
1201 North Market Street, Suite 2201
Wilmington, DE 19801
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VIA ELECTRONIC MAIL

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Attorney for Plaintiff

VIA ELECTRONIC MAIL

/s/ William B. Raich

William B. Raich

Exhibit 10 to NS's MIL No. 2

PAGES: 1-230

EXHIBITS: 1-12

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE
NO. C.A. NO. 21-1015 (GBW)

_____)
NIPPON SHINYAKU CO., LTD.,)
Plaintiff,)
vs.)
SAREPTA THERAPEUTICS, INC.,)
Defendant.)
_____)
SAREPTA THERAPEUTICS, INC.,)
Defendant and)
Counter-Plaintiff)
vs.)
NIPPON SHINYAKU CO., LTD and)
NS PHARMA, INC.,)
Plaintiffs and)
Counter-Defendants.)
_____)

VIDEOTAPED DEPOSITION OF SAREPTA
THERAPEUTICS BY BRIAN T. FORSA, called as a witness
by and on behalf of Nippon Shinyaku, pursuant to
the applicable provisions of the Federal Rules of
Civil Procedure, Rule 30(b)(6), before P. Jodi
Ohnemus, RPR, RMR, CRR, CA-CSR #13192, NH-LSR #91,
MA-CSR #123193, and Notary Public, within and for
the Commonwealth of Massachusetts, at Burns &
Levinson, 125 High Street, Boston, Massachusetts,
on Wednesday, June 14, 2023, commencing at 9:14
a.m.

NIPPON SHINYAKU vs SAREPTA THERAPEUTICS
 Brian Forsa June 14, 2023 30(b)(6), [REDACTED]

Job AMG1077
 Pages 2..5

<p style="text-align: right;">Page 2</p> <p>1 APPEARANCES:</p> <p>2</p> <p>3 MORGAN, LEWIS & BOCKIUS LLP</p> <p>4 BY: Krista Vink Venegas, Ph.D., Esq.</p> <p>5 Michael Sikora, Esq.</p> <p>6 110 North Wacker Drive</p> <p>7 Chicago, IL 60606-1511</p> <p>8 312 324-1736</p> <p>9 Krista.venegas@moganlewis.com</p> <p>10 Michael.sikora@morganlewis.com</p> <p>11 For Nippon Shinyaku Co., Ltd.</p> <p>12</p> <p>13</p> <p>14 FINNEGAN, HENDERSON, FARABOW, GARRETT</p> <p>15 & DUNNER, LLP</p> <p>16 BY: Ryan P. O'Quinn, Esq.</p> <p>17 Kaitlyn Pehrson, Esq.</p> <p>18 1875 Explorer Street, Suite 800</p> <p>19 Reston, VA 20190-6023</p> <p>20 571 203-2700</p> <p>21 Ryan.o'quinn@finnegan.com</p> <p>22 Kaitlyn.pehrson@finnegan.com</p> <p>23 For Sarepta Therapeutics, Inc.</p> <p>24</p> <p>25</p>	<p style="text-align: right;">Page 3</p> <p>1 APPEARANCES: (CONT'D)</p> <p>2</p> <p>3 ALSO PRESENT:</p> <p>4</p> <p>5 Jessica Driscoll, Esq.</p> <p>6 In-House Counsel</p> <p>7 Sarepta Therapeutics, Inc.</p> <p>8</p> <p>9 Adam Cerro, Video Operator</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>
<p style="text-align: right;">Page 4</p> <p>1 I N D E X</p> <p>2</p> <p>3 TESTIMONY OF: PAGE</p> <p>4</p> <p>5 BRIAN T. FORSA</p> <p>6 (By Ms. Venegas) 8</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p style="text-align: right;">Page 5</p> <p>1 E X H I B I T S</p> <p>2 EXHIBIT DESCRIPTION PAGE</p> <p>3</p> <p>4 Exhibit 1 Notice to Take Depositions 12</p> <p>5</p> <p>6 Exhibit 2 Nippon Shinyaku Co. Ltd. and 13</p> <p>7 NS Pharma, Inc.'s Notice of</p> <p>8 Deposition of Sarepta</p> <p>9 Therapeutics Pursuant to</p> <p>10 Fed. R. Civ. P. 30(b)(6)</p> <p>11 Exhibit 3 Brian Forsa LinkedIn profile 16</p> <p>12</p> <p>13 Exhibit 4 chart, two-page document 112</p> <p>14</p> <p>15 Exhibit 5 [REDACTED]</p> <p>16 [REDACTED]</p> <p>17 [REDACTED]</p> <p>18 Exhibit 6 Excel spreadsheet, 139</p> <p>19 SRPT-VYDS-0210696</p> <p>20 Exhibit 7 [REDACTED]</p> <p>21 [REDACTED]</p> <p>22 [REDACTED]</p> <p>23 Exhibit 8 spreadsheet, 182</p> <p>24 SRPT-VYDS-0210792</p> <p>25 [REDACTED]</p>

[illegible]

Page 101

1 [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

15 MR. O'QUINN: Objection to form.

16 [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

24 MR. O'QUINN: Objection to form.

25 You can answer that yes or no, Mr. Forsa.

NIPPON SHINYAKU vs SAREPTA THERAPEUTICS
Brian Forsa June 14, 2023 30(b)(6), [REDACTED]

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Pages 226..229

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1 I think -- yeah, I mean, we'll certainly
2 take anything you ask under advisement. So...
3 MS. VENEGAS: I appreciate that. We'll
4 leave the deposition open until we can negotiate
5 and come to an agreement on those points.
6 MR. O'QUINN: I mean, I'll point out for
7 the record we spent a lot of time today on
8 off-topic questions. So I don't know that any
9 additional time would be warranted.
10 MS. VENEGAS: Obviously we disagree that
11 much of that was off topic, but I think the record
12 will reflect we asked questions to try to probe in
13 more depth some of the deposition topics that we
14 were anticipating exploring more thoroughly and
15 were unable to do so, either as a result of lack of
16 preparation, lack of knowledge, recollection, or as
17 a result of redactions, for example.
18 So thank you. And we'll look forward to
19 following up with you offline.
20 MR. O'QUINN: Okay. Mr. Forsa, I have no
21 questions for you. Thank you.
22 [REDACTED]

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1 DEPONENT'S ERRATA SHEET
2 AND SIGNATURE INSTRUCTIONS
3
4
5 The original of the Errata Sheet has
6 been delivered to Ryan O'Quinn, Esq.
7 When the Errata Sheet has been
8 completed by the deponent and signed, a copy
9 thereof should be delivered to each party of record
10 and the ORIGINAL delivered to Krista Vink Venegas,
11 Esq., to whom the original deposition transcript
12 was delivered.
13
14
15 INSTRUCTIONS TO DEPONENT
16
17 After reading this volume of your
18 deposition, indicate any corrections or changes to
19 your testimony and the reasons therefor on the
20 Errata Sheet supplied to you and sign it. DO NOT
21 make marks or notations on the transcript volume
22 itself.
23
24
25 REPLACE THIS PAGE OF THE TRANSCRIPT WITH THE
COMPLETED AND SIGNED ERRATA SHEET WHEN RECEIVED.

Page 227

1 VIDEO OPERATOR: This suspends today's
2 video deposition of Brian Forsa. The time is 4:01
3 p.m. We're off the record.
4 (Whereupon the deposition suspended at
5 4:01 p.m.)
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Page 229

1 Commonwealth of Massachusetts
2 Middlesex, ss.
3
4
5 I, P. Jodi Ohnemus, Notary Public
6 in and for the Commonwealth of Massachusetts,
7 do hereby certify that there came before me on the
8 14th day of June, 2023, the deponent herein, who
9 was duly sworn by me; that the ensuing examination
10 upon oath of the said deponent was reported
11 stenographically by me and transcribed into
12 typewriting under my direction and control; and
13 that the within transcript is a true record of the
14 questions asked and answers given at said
15 deposition.
16
17 I FURTHER CERTIFY that I am neither
18 attorney nor counsel for, nor related to or
19 employed by any of the parties to the action
20 in which this deposition is taken; and, further,
21 that I am not a relative or employee of any
22 attorney or financially interested in the outcome
23 of the action.
24
25 IN WITNESS WHEREOF I have hereunto set my
hand and affixed my seal of office this
5th day of June, 2023, at Waltham.
Jodi Ohnemus

P. Jodi Ohnemus, RPR, RMR, CRR,
CSR, Notary Public,
Commonwealth of Massachusetts
My Commission Expires:
3/3/2028

NIPPON SHINYAKU vs SAREPTA THERAPEUTICS
Brian Forsa June 14, 2023 30(b)(6), [REDACTED]

Job AMG1077
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Page 230

1 ATTACH TO DEPOSITION OF: BRIAN T. FORSA
2 CASE: NIPPON SHINYAKU VS. SAREPTA THERAPEUTICS
3
4 ERRATA SHEET
5
6 INSTRUCTIONS: After reading the transcript of your
7 deposition, note any change or correction to your
8 testimony and the reason therefor on this sheet.
9 DO NOT make any marks or notations on the
10 transcript volume itself. Sign and date this
11 errata sheet (before a Notary Public, if required).
12 Refer to page 228 of the transcript for errata
13 sheet distribution instructions.
14 PAGE LINE
15
16 CHANGE: _____
17 REASON: _____
18 CHANGE: _____
19 REASON: _____
20 CHANGE: _____
21 REASON: _____
22 CHANGE: _____
23 REASON: _____
24 CHANGE: _____
25 REASON: _____
26
27 I have read the foregoing transcript of
28 my deposition and except for any corrections or
29 changes noted above, I hereby subscribe to the
30 transcript as an accurate record of the statements
31 made by me.
32
33 BRIAN T. FORSA
34
35 Subscribed and sworn to before me
36 this _____ day of _____, 2023.
37
38 Notary Public
39 My Commission Expires:

Exhibit 11 to NS's MIL No. 2

1 IN THE UNITED STATES DISTRICT COURT

2 FOR THE DISTRICT OF DELAWARE

3 NO. C.A. NO. 21-1015 (GBW)

4 *****

5 NIPPON SHINYAKU CO., LTD.,

6 Plaintiff

7 vs.

8 SAREPTA THERAPEUTICS, INC.,

9 Defendant and Counter-Plaintiff

10 _____

11 SAREPTA THERAPEUTICS, INC.,

12 Defendant and
13 Counter-Plaintiff,

14 vs.

15 NIPPON THERAPEUTICS CO., LTD and
16 NS PHARMA, INC.,

17 Plaintiffs and
18 Counter-Defendants,

19 *****

20

21

22

23

24

<p style="text-align: right;">Page 2</p> <p>1</p> <p>2</p> <p>3</p> <p>4</p> <p>5</p> <p>6</p> <p>7</p> <p>8 VIDEOTAPED DEPOSITION OF:</p> <p>9 RYAN WONG</p> <p>10 FINNEGAN, HENDERSON, FARABOW,</p> <p>11 GARRETT & DUNNER, LLP</p> <p>12 Two Seaport Lane</p> <p>13 Boston, Massachusetts</p> <p>14 July 13, 2023 9:10 a.m.</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22 Darlene M. Coppola</p> <p>23 Registered Merit Reporter</p> <p>24 Certified Realtime Reporter</p>	<p style="text-align: right;">Page 3</p> <p>1 APPEARANCES:</p> <p>2 Representing the Plaintiffs and</p> <p>3 Counter-Claim Defendants Nippon</p> <p>4 Shinyaku Co., Ltd. and NS Pharma, Inc.:</p> <p>5 MORGAN, LEWIS & BOCKIUS LLP</p> <p>6 110 North Wacker Drive</p> <p>7 Chicago, IL 60606</p> <p>8 BY: MICHAEL SIKORA, ESQUIRE</p> <p>9 KRISTA VINK VENEGAS, PH.D.</p> <p>10 T 312.324.1000</p> <p>11 E michael.sikora@morganlewis.com</p> <p>12 krista.venegas@morganlewis.com</p> <p>13</p> <p>14 Representing the Defendant Counter-Claim</p> <p>15 Plaintiffs SAREPTA Therapeutics, Inc.:</p> <p>16 FINNEGAN, HENDERSON, FARABOW,</p> <p>17 GARRETT & DUNNER, LLP</p> <p>18 1875 Explorer Street</p> <p>19 Suite 800</p> <p>20 Reston, VA 20190</p> <p>21 BY: RYAN P. O'QUINN, ESQUIRE</p> <p>22 T 571.203.2700</p> <p>23 E ryan.o'quinn@finnegan.com</p> <p>24</p>
<p style="text-align: right;">Page 4</p> <p>1 Also Present:</p> <p>2 Jessica Driscoll, In-house counsel, Sarepta</p> <p>3 Nicholas Lobraco, Stout (Via telephone)</p> <p>4 Gayle Ashton, Videographer</p> <p>5</p> <p>6</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p style="text-align: right;">Page 5</p> <p>1 INDEX</p> <p>2 EXAMINATION</p> <p>3 Witness Name Page</p> <p>4 RYAN WONG</p> <p>5 Direct By Ms. Sikora 8</p> <p>6 Cross By MR. O'QUINN 269</p> <p>7 Re-Direct By MR. SIKORA 271</p> <p>8</p> <p>9 EXHIBITS</p> <p>10 Exhibit Description Page</p> <p>11 Exhibit 1 Rule 30(b)(6) 11</p> <p>12 Deposition Notice</p> <p>13 Exhibit 2 Notice of Deposition 17</p> <p>14 Exhibit 3 LinkedIn profile 25</p> <p>15 Exhibit 4 E-mail and attachments; 54</p> <p>16 Sarepta Vyondys 0220619 through 0649</p> <p>17 Exhibit 5 [REDACTED]</p> <p>18 [REDACTED]</p> <p>19 [REDACTED]</p> <p>20 Exhibit 6 E-mail dated December 79</p> <p>21 27, 2019, Sarepta</p> <p>22 Vyondys 0218928 through 8935</p> <p>23 Exhibit 7 E-mail dated August 20, 99</p> <p>24 2021 with attached</p> <p>25 [REDACTED]</p> <p>26 [REDACTED]</p>

EXHIBITS			Page 6
Exhibit	Description		Page
Exhibit 8	E-mail dated January 12, 2021 with attached		113
Exhibit 9	E-mail dated January 14, 2021 with attached		115
Exhibit 10			
Exhibit 11	Native Excel Document, Sarepta Vyondys 0213311		131
Exhibit 12			

Page 8

1 Jessica Driscoll from Sarepta.

2 THE VIDEOGRAPHER: Would the

3 court reporter, Darlene Coppola, please swear

4 in the witness.

5

6 RYAN WONG,

7 a witness called for examination by

8 counsel for the Plaintiff Nippon Shinyaku Co.,

9 Ltd., having been satisfactorily identified by

10 the production of his driver's license and

11 being first duly sworn by the Notary Public,

12 was examined and testified as follows:

13

14 THE STENOGRAPHER: Thank you.

15 You may proceed.

16

17 DIRECT EXAMINATION

18 BY MR. SIKORA:

19 Q. Good morning, Mr. Wong. As I

20 mentioned before, my name's Mike Sikora, and

21 I'm an attorney for Nippon Shinyaku and NS

22 Pharma in the litigation.

23 Have you ever been deposed before?

24 A. No.

Page 7

1 PROCEEDING

2

3 (Commencing at 9:10 a.m.)

4

5 THE VIDEOGRAPHER: Good morning.

6 We are now on the record. This is the

7 videographer speaking, Gayle Ashton, with AMG

8 Digital Reporting.

9 Today's date is July 13, 2023, and the

10 time is 9:10 a.m. We are here at Finnegan,

11 2 Seaport Lane, Boston, Massachusetts, to take

12 the video deposition of Ryan Wong in the

13 matter of Nippon Shinyaku versus Sarepta

14 Therapeutics.

15 Would counsel please introduce

16 themselves for the record.

17 MR. SIKORA: This is Mike Sikora

18 on behalf of Nippon Shinyaku and NS Pharma a

19 from the Morgan Lewis law firm and with me is

20 my co-counsel, Krista Venegas.

21 MR. O'QUINN: Ryan O'Quinn from

22 Finnegan LLP representing Sarepta

23 Therapeutics, the University of Western

24 Australia, and the witness. With me is

Page 9

1 Q. Okay. So we'll go through kind of the

2 preliminaries, but if you have any questions

3 throughout the day on procedure, just please

4 let us know, and we're happy to answer it.

5 So you understand that all of the

6 questions that I pose to you will be under --

7 answered under oath truthfully to the best of

8 your ability today?

9 A. Yes.

10 Q. And is there any reason today that you

11 think you would be unable to provide truthful

12 answers to the best of your ability, whether

13 medical, health, or otherwise?

14 A. No.

15 Q. And so you're already doing a great

16 job of this, but we'll need verbal responses

17 so that it gets taken down for the record. I

18 might remind you or something if it doesn't

19 happen, but no "uh-huhs," "ahs," things like

20 that, or -- so we'll address those.

21 And then we'll take a series of breaks

22 throughout the day. Usually, we stop about

23 every hour, but if you ever need a break

24 before or you want to continue going longer,

Page 42

1 [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

12 MR. O'QUINN: Objection to form.

13 Compound.

14 **A. Can you repeat the question.**

15 BY MR. SIKORA:

16 [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Page 44

1 MR. O'QUINN: Outside the scope.

2 You can answer, if you know.

3 [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

11 MR. O'QUINN: Objection to form.

12 Vague. Outside the scope.

13 [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

21 MR. O'QUINN: Same objections.

22 [REDACTED]

[REDACTED]

24 BY MR. SIKORA:

Page 43

1 [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

7 MR. O'QUINN: This is outside

8 the scope of Mr. Wong's topics.

9 You can answer if you know in your

10 personal capacity.

11 [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

18 MR. O'QUINN: Objection to form.

19 Vague. Outside the scope.

20 You can answer, if you know.

21 [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Page 45

1 [REDACTED]

[REDACTED]

[REDACTED]

4 MR. O'QUINN: Same objections.

5 [REDACTED]

[REDACTED]

[REDACTED]

9 MR. O'QUINN: Same objections.

10 [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

17 MR. O'QUINN: Same objections.

18 [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD.,)
)
Plaintiff,)
)
v.) C.A. No. 21-1015 (JLH)
)
SAREPTA THERAPEUTICS, INC.,)
)
Defendant.)

SAREPTA THERAPEUTICS, INC. and THE)
UNIVERSITY OF WESTERN AUSTRALIA,)
)
Defendant/Counter-Plaintiffs,)
)
v.)
)
NIPPON SHINYAKU CO., LTD.)
and NS PHARMA, INC.)
)
Plaintiff/Counter-Defendants.)

**SAREPTA THERAPEUTICS, INC. AND THE UNIVERSITY OF WESTERN
AUSTRALIA’S RESPONSE TO NIPPON SHINYAKU CO., LTD. AND NS PHARMA,
INC.’S MOTION *IN LIMINE* NO. 2 TO PRECLUDE
ARGUMENT OR EVIDENCE ON UNDISCLOSED FACTS**

Sarepta does not intend to offer any evidence that has not been available to NS. In what should properly be filed as four separate motions, NS's MIL No. 2 improperly seeks to preclude four broad categories of evidence that *have* been available to NS. Sarepta and UWA should be allowed to rely on relevant evidence at trial that supports their defenses and counterclaims and which, contrary to NS's representations, NS has had ample opportunity to probe and develop. To the extent NS complains certain discovery has not been provided, such information is (i) not available to Sarepta or UWA and/or (ii) irrelevant to this case.

Exclusion under Rule 37(c) is reserved for information that a party "fails to provide . . . or identify" as required by Rule 26. Sarepta and UWA have complied with Rule 26 in good faith, and NS's eleventh-hour complaints do not justify broad preclusion of evidence and information. "The exclusion of critical evidence is an extreme sanction, not normally to be imposed absent a showing of willful deception or flagrant disregard of a court order by the proponent of the evidence." *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 791-92 (3d Cir. 1994) (cleaned up).

NS has not demonstrated that either the *Pennypack* factors or Rule 403 favor exclusion. Where there have been and will be no "eve-of-trial disclosures of new information," there can be no prejudice. For each of the topics identified, NS has had ample opportunity to depose multiple witnesses and has been provided additional information in response to its follow-up requests. NS sought the assistance of the Court regarding certain topics and those issues were conclusively resolved. *See* D.I. 254; D.I. 271; D.I. 348. NS has made no showing of bad faith because there has been none. The broad categories of information NS seeks to exclude are relevant to multiple issues in this case, including validity and damages issues. Under a full analysis, the *Pennypack* factors weigh in favor of denial of NS's motion in its entirety. *See UCB, Inc. v. KV Pharm. Co.*, No. 08-223-JJF, D.I. 193, slip op. at 5-6 (D. Del. Mar. 9, 2010) (Ex. A); *Walker Digital, LLC v. Google*

Inc., Case No. 11-309-SLR, D.I. 368, slip op. at 2-4 (D. Del. June 14, 2013) (Ex. B).

A. Accused Product Selection: Sarepta has provided ample discovery relating to the development of VYONDYS 53[®], including hundreds of documents relating to selection of the sequence. Among these documents is a formal report memorializing the sequence selection process (“Report”) which describes the extensive testing performed by Sarepta and two collaborators on multiple clinical candidates. NS also took *five* depositions of witnesses with knowledge of this topic, including two former Sarepta employees, [REDACTED] and who collectively produced more than 500 documents. NS’s belated allegations of deficient 30(b)(6) and fact witness testimony do not justify its sweeping request. NS did not raise any alleged deficiencies during discovery, did not hold open the relevant depositions, and did not follow up via letter correspondence or motions practice. Sarepta and UWA should be allowed to rely at trial on the information that has been made available to NS. Although Sarepta asserted privilege over Sarepta’s final decision to select its clinical candidate which became VYONDYS 53[®], Sarepta did *not* assert privilege over the testing or statements in the Report. At trial, Sarepta’s presentation of evidence will be consistent with the non-privileged evidence that was available to NS in discovery.

B. Other Sarepta Exon 53 Research: At the request of NS, Sarepta produced responsive documents located through a reasonable search. In response to NS’s additional requests for the data underlying the Exon 53-related research of former employees Drs. Kole and Sazani, Sarepta conducted a reasonable investigation and produced the resulting responsive information (including native files of the underlying data as a courtesy). *See* Ex. C. NS did not follow up with additional requests or otherwise indicate that the issue was not resolved, and later failed to show that its third-party subpoenas to Dr. Kole and Dr. Sazani should be enforced.

C. Damages – Licensing Activity: NS has made no showing as to why “knowledge

of the negotiations” of various licenses is relevant¹ to any claim or defense in this case, nor has it defined the scope of what that “knowledge” would encompass. As NS’s vague and overbroad motion alludes, the text of those documents speaks for itself. NS also did not follow up on license-related discovery, did not hold open the relevant depositions, did not follow up via letter correspondence, and did not file a motion to compel. As for the [REDACTED] Agreement, the Special Master’s denial of NS’s motion to compel was based on a lack of relevance. D.I. 254.² Sarepta has no intention of relying on the non-public terms of an irrelevant agreement at trial. The information on licensing activity that *has* been made available to NS, however, is highly relevant to damages. As such, NS’s belated, overbroad motion should be denied.

D. Damages – Alternative Products: Sarepta opposed certain discovery into detailed information regarding products other than VYONDYS 53[®] based on a lack of relevance—and the Special Master agreed. D.I. 348. NS also criticizes Sarepta’s witnesses’ inability to specifically quantify the potential effect of ELEVIDYS[®] on future sales of VYONDYS 53[®], but omits that the witnesses in question were deposed just one week before and three weeks after the FDA’s limited approval of ELEVIDYS[®] on June 22, 2023.³ NS’s frustration at the inability of witnesses to *specifically* quantify the impact of uncertain future events should not result in it being able to broadly exclude *general* reference to these other factors.

¹ Tellingly, NS did not specifically identify “knowledge of negotiations” as a topic on which it sought 30(b)(6) testimony.

² NS told the Court just two weeks ago that its objections to the Special Master’s decision were moot and could be disregarded. D.I. 526 at 3.

³ Even today, the scope of the future population of patients eligible for treatment is still uncertain, as it is subject to the FDA’s ongoing consideration of Sarepta’s request to expand the label indication beyond the currently indicated 4- and 5-year-old label. *See* Sarepta Therapeutics Announces U.S. FDA Acceptance of an Efficacy Supplement to Expand the ELEVIDYS Indication (Feb. 16, 2024), *available at* <https://investorrelations.sarepta.com/news-releases/news-release-details/sarepta-therapeutics-announces-us-fda-acceptance-efficacy>.

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April 25, 2024

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CERTIFICATE OF SERVICE

I hereby certify that on April 25, 2024, copies of the foregoing were caused to be served upon the following in the manner indicated:

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EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UCB, INC. and CELLTECH :
MANUFACTURING CA, INC., :
 :
Plaintiffs, :
 :
v. : Civil Action No. 08-223-JJF
 :
KV PHARMACEUTICAL COMPANY, :
 :
Defendant. :
 :

Scott K. Reed, Esquire; Steven C. Kline, Esquire and Ha Kung Wong, Esquire of FITZPATRICK, CELLA, HARPER & SCINTO, New York, New York.

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MEMORANDUM OPINION

March 9, 2010
Wilmington, Delaware.


Farnan, District Judge.

Pending before the Court are six motions in limine, three filed by each side. Plaintiffs UCB, Inc. and Celltech Manufacturing CA, Inc. (collectively "Plaintiffs") filed their Motion In Limine No. 1 To Preclude Defendant From Relying On A Newly-Disclosed On-Sale Bar Defense (D.I. 151), No. 2 To Preclude Defendant From Introducing At Trial Argument Or Evidence Concerning Its New Non-Infringement Theory (D.I. 152), and No. 3 To Preclude Defendant From Introducing Testimony Of Dr. Chambliss At Trial Concerning The Date Of Invention Of The Patent-In-Suit Contrary To The Assumptions In His Expert Report. (D.I. 153.) At the same time Defendant KV Pharmaceutical Company filed its Motion In Limine No. 1 To Hold Plaintiffs To Their 30(b)(6) Testimony Concerning Date Of Invention (D.I. 154), No. 2 To Preclude Testimony Regarding The F2 Similarity Factor (D.I. 155), and No. 3 To Strike The Supplemental Expert Report Of Stephen R. Byrn And Preclude Any Related Testimony. (D.I. 156.) For the reasons discussed, and because the upcoming trial is a bench trial, these Motions will be denied.

I. BACKGROUND

This is a patent infringement action brought by Plaintiffs asserting that Defendant has infringed on United States Patent No. 6,344,215 ("the '215 patent"). The '215 patent pertains to

pharmaceutical dosage forms that provide a modified release of methlyphenidate for the treatment of attention deficit hyperactivity disorder ("ADHD"). Plaintiffs initiated this action in response to Defendant submitting an ANDA to the United States Food and Drug Administration seeking approval to sell a generic version of Plaintiffs' Metadate CD product. (D.I. 128 at 1.) Plaintiffs assert that the Metadate CD product is the commercial embodiment of the '215 patent. The instant suit alleges infringement of only claims 1 and 2 of the '215 patent.

The Court issued its claim construction ruling on August 18, 2009 (D.I. 93, 94) and the parties completed discovery in December 2009. A pre-trial conference was held March 4, 2010 and a bench trial is scheduled to begin on April 12, 2010.

II. LEGAL STANDARD ON THE EXCLUSION OF EVIDENCE AND TESTIMONY

Under Fed. R. Civ. P. 26(a) and (e) parties are required to make a number of disclosures and supplements to disclosures and responses. This standard is further addressed in Fed. R. Civ. P. 37(c)(1) which states that "[i]f a party fails to provide information or identity of a witness as required by Rule 26(a) or (e) the party is not allowed to use that information or witness to supply evidence . . . unless the failure was substantially justified or is harmless."

The Third Circuit and this Court have focused on a series of

factors in evaluating harmlessness and substantial justification:

In determining whether a failure to disclose is harmless courts consider such factors as: (1) the importance of the information withheld; (2) the prejudice or surprise to the party against whom the evidence is offered; (3) the likelihood of disruption of the trial; (4) the possibility of curing the prejudice; (5) the explanation for the failure to disclose; and (6) the presence of bad faith or willfulness in not disclosing the evidence (the "Pennypack factors").

Boehringer Ingelheim Int'l GMBH v. Barr Labs. Inc., Civ. No. 05-700-JJF, 2008 U.S. Dist. LEXIS 53475, *4-5 (D. Del. July 15, 2008) (citing Konstantopoulos v. Westvaco Corp., 112 F.3d 710, 719 (3d Cir. 1997); see also, Meyers v. Pennypack Woods Home Ownership Ass'n, 559 F.2d 894, 904-905 (3d Cir. 1977)). Lastly, "the exclusion of critical evidence is an 'extreme' sanction, not normally to be imposed absent a showing of wilful deception or 'flagrant disregard' of a court order by the proponent of the evidence." Konstantopoulos, 112 F.3d at 719 (quoting Meyers, 559 F.2d at 905).

III. PLAINTIFFS' MOTION IN LIMINE NO. 1

A. Parties' Contentions

Through its Motion in Limine No. 1 (D.I. 151), Plaintiffs request the Court to preclude Defendant from relying on the on-sale bar defense. Plaintiffs contend that Defendant should be precluded from asserting an on-sale defense bar, under 35 U.S.C. § 102(b), because Defendant did not assert such a defense during discovery. (Id.) Plaintiffs further argue that the untimely

assertion of the on-sale bar defense is both unjustified, because Defendant possessed the relevant discovery long before asserting the defense, and unduly prejudicial because Plaintiffs were unable to properly prepare for the defense. (Id.) Plaintiffs also contend that the fact that they control the relevant documents does not eliminate the prejudice of untimeliness. (D.I. 178.)

Defendant opposes the instant Motion. (D.I. 172.) In doing so, Defendant contends that any delay in the assertion of the on-sale bar defense was a direct result of Plaintiffs' discovery failures. (Id.) Specifically, Defendant argues that Plaintiffs failed to disclose the prior Eurand Litigation and the date of invention. (Id.) Defendant asserts that the supplementation of interrogatories to include the on-sale bar defense was proper as timely following the disclosure of the relevant evidence by Plaintiffs. (Id.) Lastly, Defendant argues that there is no prejudice if the defense is allowed because all of the relevant documents and information are in Plaintiffs' control.

B. Decision

The Court concludes that preclusion of Defendant's on-sale bar defense is not warranted when the on-sale bar defense is evaluated under Fed. R. Civ. P. 37 and the Pennypack factors. First, the availability of the necessary information is disputed, as is evidenced further by the ongoing dispute on the date of

invention. The parties have submitted a number of exhibits claiming to show evidence of timeliness and untimeliness, but these documents primarily demonstrate the ongoing discovery disputes between the parties and the statements within them are primarily attorney comments.

However, the Court is able to determine that preclusion is not warranted because Plaintiffs have not shown any actual harm or prejudice they will face if the on-sale bar defense is allowed. Although Plaintiffs argue they were denied discovery regarding the issue, they do not cite to any particular discovery they were unable to complete. The Court finds on the record presented that Plaintiffs are not prejudiced by the late assertion of the defense as seen by their ability to respond to Defendant's Summary Judgment Motion on the issue.

IV. PLAINTIFFS' MOTION IN LIMINE NO. 2 AND DEFENDANT'S MOTION IN LIMINE NO. 3

Plaintiffs' Motion in Limine No. 2 and Defendant's Motion in Limine No. 3 both relate to the same subject matter, Defendant's non-infringement theory and the supplemental report of Plaintiffs' expert Dr. Byrn.

A. Parties' Contentions

By their Motion in Limine No. 2, Plaintiffs seek the preclusion of Defendant's non-infringement argument. (D.I. 152.) Plaintiffs contend that Defendant was untimely in presenting the

argument of non-infringement based on the inapplicability of Claim 1 of the '215 patent to the accused product. Plaintiffs further contend that Defendant did not present the argument that the ratio of immediate release and extended release beads was required to be the same in the accused product as in the patent claim in a timely manner. (Id.) Defendant responds that it has long asserted that there could be no infringement because the accused product did not fit within the table that provides the ratios in the '215 patent. (D.I. 173.) Plaintiffs add that if Defendant's argument is permitted, they should be permitted to rely on the Supplemental Report of Dr. Byrn. (D.I. 152.)

Defendant's Motion in Limine No. 3 seeks to strike the Supplemental Report of Dr. Byrn and preclude any related testimony. (D.I. 156.) Defendant contends that Plaintiffs' Expert Dr. Byrn's Supplemental Report, which was issued after a Motion for Summary Judgment filed by Defendant, should be struck as untimely. (Id.) Plaintiffs counter that the supplemental report was necessary and timely because it responded to late opinions raised by Defendant. (D.I. 177.) Plaintiffs also assert that inclusion of the supplemental report is not prejudicial to Defendant because it was presented with adequate time to investigate. (Id.)

B. Decision

Plaintiffs' Motion in Limine No. 2 will be denied because,

in the Court's view, Defendant has been timely in asserting the instant defense. Defendant has argued since claim construction that its product does not infringe upon the asserted claims of the '215 patent based on the ratios of the table it has long disputed. Plaintiffs have addressed and argued on the issue of the ratio of the beads in the accused product compared to the ratios in the claim language in the context of summary judgment. Thus, although the precise argument of the ratio of beads in the tested accused product may not have been expressly disclosed, the issue of ratios in the context of non-infringement and indefiniteness has long been known.

Defendant's Motion in Limine No. 3 will also be denied. The Court concludes that striking the supplemental report is not warranted because its assertions are consistent with Dr. Byrn's prior statements and it was entered to address Defendant's summary judgment motion. Thus, Defendant will not be prejudiced by the admission of the supplemental report.

In sum, the Court concludes that both Motions in Limine relating to non-infringement will be denied.

V. PLAINTIFFS' MOTION IN LIMINE NO. 3 AND DEFENDANT'S MOTION IN LIMINE NO. 1

Plaintiffs' Motion in Limine No. 3 and Defendant's Motion in Limine No. 1 both relate to the parties' ongoing dispute about the date of the invention embodied in the '215 patent.

A. Parties' Contentions

Through the instant motions, each side seeks to limit what the other can cite as the date of the invention. By their Motion In Limine No. 3 (D.I. 153), Plaintiffs seek to limit expert Dr. Chambliss to a 1996 date of invention based on assumptions made in Dr. Chambliss' expert report. Plaintiffs contend that, in his expert report, Dr. Chambliss made assumptions regarding prior art related to the '215 patent with both a 1996 and 2000 date of invention, but that Defendant specifically accepted a 1996 date. (Id.) Thus, Plaintiffs contend, Defendant should be limited to a 1996 date of invention. Defendant counters that Dr. Chambliss was merely being prudent in providing prior art information based on both dates because Plaintiffs had not fulfilled their obligation to establish the date of invention at that time. (D.I. 174.)

Similarly, Defendant seeks to limit Plaintiffs to a 2000 date of invention based on the testimony given in the 30(b)(6) deposition. (D.I. 154.) Defendant argues that because the 30(b)(6) witness stated that Plaintiffs did not know the date of invention and only that it was within the disclosed documents, Plaintiffs should be held to the constructive date of invention of 2000 based on the date the patent application was filed. (Id.) Plaintiffs counter that Defendant's attempts to obtain the date of invention in the context of a 30(b)(6) deposition were

improper and should have been saved for the deposition of an expert, and that Defendant accepted a 1996 date of invention through its Motion For Summary Judgment based on the on-sale bar. (D.I. 175.)

B. Decision

The presumed date of invention is the date the patent application is filed, however, an earlier date of invention can be established. See Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc., 585 F. Supp. 2d 568, 575 (D. Del. 2008) (noting the rebuttal presumption that the date of invention is the filing date). In establishing a pre-filing date of invention, a patent holder has the burden of production, but a party challenging the patent has the burden of proof. Mahurkar v. C.R. Bard, Inc., 79 F.3d 1572, 1576 (Fed. Cir. 1996).

There is no surprise to either party that two dates of invention were potentially at issue in this litigation and will now require proof at trial. In the circumstances presented, neither party is prejudiced, and therefore, the motions of each will be denied.

VI. DEFENDANT'S MOTION IN LIMINE NO. 2

The F2 similarity factor is a test used to compare the dissolution profiles of pharmaceuticals. Plaintiffs contend that the F2 similarity factor can be used to prove that the accused

product infringes on the '215 patent.

Defendant's Motion in Limine No. 2 (D.I. 155) seeks to preclude Plaintiffs from using testimony concerning the F2 similarity factor. Defendant argues that the F2 similarity factor is inappropriate in the context of evaluating infringement and contrasts with Plaintiffs' and the Court's construction of the claim term "approximately." (Id.) Also, Defendant contends that Plaintiffs did not disclose their intention to use the F2 similarity factor in a timely fashion. (D.I. 182.) Plaintiffs counter that the F2 similarity factor is an appropriate and widely accepted method of comparing dissolution rates and that they disclosed the intent to use the method as early as the first expert reports. (D.I. 176.)

In the Court's view, Plaintiffs' intention to use the F2 similarity factor as proof of infringement was brought in a timely manner. It was addressed in Plaintiffs' first expert report by Dr. Byrn. (See D.I. 176 Ex. 1.) Second, the use of the F2 similarity factor is not inconsistent with the claim term "approximately." Although the terms "approximately" and "similarity" may not be synonyms, they are not mutually exclusive terms. Thus, it is possible that the F2 similarity factor could be used in demonstrating infringement in the scope of Claim 1 as it has been construed. Lastly, Defendant's contentions on the probative value of the F2 similarity factor do not warrant the

exclusion of the test all together. Thus, Defendant's Motion will be denied.

VII. CONCLUSION

For the reasons discussed, Plaintiffs' Motion In Limine No. 1 To Preclude Defendant From Relying On A Newly-Disclosed On-Sale Bar Defense (D.I. 151), No. 2 To Preclude Defendant From Introducing At Trial Argument Or Evidence Concerning Its New Non-Infringement Theory (D.I. 152), and No. 3 To Preclude Defendant From Introducing Testimony Of Dr. Chambliss At Trial Concerning The Date Of Invention Of The Patent-In-Suit Contrary To The Assumptions In His Expert Report (D.I. 153) will be denied. Additionally, Defendant's Motion In Limine No. 1 To Hold Plaintiffs To Their 30(b)(6) Testimony Concerning Date Of Invention (D.I. 154), No. 2 To Preclude Testimony Regarding The F2 Similarity Factor (D.I. 155), and No. 3 To Strike The Supplemental Expert Report Of Stephen R. Byrn And Preclude Any Related Testimony (D.I. 156) will also be denied.

An appropriate order will be entered.

EXHIBIT B

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WALKER DIGITAL, LLC,)	
)	
Plaintiff,)	
)	
v.)	Civ. No. 11-309-SLR
)	
GOOGLE INC., MICROSOFT CORP,)	
and SAMSUNG)	
TELECOMMUNICATIONS)	
AMERICA LLC)	
)	
Defendants.)	

MEMORANDUM ORDER

At Wilmington this ^{14th} day of June, 2013, having considered plaintiff Walker Digital, LLC's ("Walker Digital") motion to exclude testimony regarding commercial success of the accused Google products and services (D.I. 300), and defendant Microsoft Corporation's ("Microsoft") motion to strike untimely infringement theories (D.I. 312), as well as the papers submitted therewith;

IT IS ORDERED that:

1. **Background.** On April 11, 2011, Walker Digital filed suit in this district against multiple defendants, including Google Inc. ("Google"), Samsung Telecommunications America, LLC ("Samsung"), and Microsoft alleging infringement of United States Patent No. 6,199,014 ("the '014 patent"). (D.I. 1) Samsung answered and counterclaimed against Walker Digital on June 20, 2011, Google on June 21, 2011, and Microsoft on July 11, 2011. (D.I. 36, 39, 55) Walker Digital answered Google and

Samsung's counterclaims on July 11, 2011 and Microsoft's on August 1, 2011. (D.I. 53, 54, 64) Fact discovery closed on October 22, 2012. (D.I. 138) The court has jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

2. **Standard.** "Trial judges are afforded wide discretion in making rulings on the admissibility of evidence." *Quinn v. Consolidated Freightways Corp. of Delaware*, 283 F.3d 572, 576 (3d. Cir. 2002) (citations omitted). "[T]he exclusion of critical evidence is an 'extreme' sanction, not normally to be imposed absent a showing of willful deception or 'flagrant disregard' of a court order by the proponent of the evidence." *Meyers v. Pennypack Woods Home Ownership Ass'n*, 559 F.2d 894, 904 (3d Cir. 1977), rev'd on other grounds. Appropriate sanctions for violation of a scheduling order by a failure to disclose or supplement with respect to Fed. R. Civ. P. ("Rule") 26(a) or (e), are provided at Rule 37(c). Courts in the Third Circuit consider five factors when deciding whether to preclude evidence under Rule 37:

(1) the prejudice or surprise to a party against whom the evidence is offered; (2) ability of the injured party to cure the prejudice; (3) likelihood of disruption of trial; (4) bad faith or willfulness involved in not complying with the disclosure rules; and (5) importance of the evidence to the proffering party.

GlobespanVirata, Inc. v. Texas Instruments, Inc., Civ. No. 03–2854, 2005 WL 1638136 at *2 (D.N.J. July 12, 2005) (citing *Quinn*, 283 F.3d at 577) (Pennypack factors).

3. **Motion to exclude testimony.** On August 13, 2012, Walker Digital served interrogatories requesting financial information regarding the accused instrumentalities, two months before close of fact discovery. On September 17, 2012, Google provided no substantive information, instead, offering to "meet and confer" with Walker Digital.

Walker Digital asserted that Google's revenue data was relevant to the issue of commercial success, a secondary consideration of non-obviousness. Google disagreed, stating that the court bifurcated the case and allowed the parties to only seek "limited financial discovery." (D.I. 100 at 4) The parties conferred from September 19-21, 2012 without resolution; however, Google offered a 30(b)(6) witness to testify about limited financial matters. (D.I. 346 at 3) Walker Digital then filed a motion to compel the financial data on October 22, 2012, the day fact discovery closed. (D.I. 237) The court denied the motion per its policy that discovery motions are not to be filed in patent cases absent prior approval, but invited the parties to schedule an in-person discovery conference to resolve any disputes. (D.I. 264) On October 26, 2012, Walker Digital took the deposition of Google's 30(b)(6) witness, which included financial topics and information regarding commercial success. (D.I. 347, ex. 6 at 76-78, 103:8-104:11) On December 21, 2012, Google supplemented its interrogatory responses with additional financial data, including revenue "attributable to Street View generally," for May 2009-September 2012.¹ (D.I. 346 at 6; D.I. 300, ex. D)

4. After review, the court concludes that the financial data supplied in the supplemental interrogatory is not well beyond or inconsistent with the testimony of Google's 30(b)(6) witness. Further, Walker Digital had ample opportunity to seek the court's assistance in obtaining financial data earlier, but did not do so. After Google supplemented its interrogatory response, the court held a discovery conference on January 9, 2013 and a status conference on February 6, 2013. Walker Digital

¹Google avers the information was consistent with its expert's deposition testimony. (D.I. 346 at 6)

communicated to the court that there were no issues with respect to Civ. No. 11-309 for discussion at the status conference. Walker Digital had the opportunity to depose a 30(b)(6) witness on financial topics and chose not to follow up with the court after the denial of its motion to compel. Nor has Walker Digital shown evidence of bad faith as required for exclusion. For these reasons, on balance, the various *Pennypack* factors weigh against precluding Google's disclosed financial data. The court denies Walker Digital's motion to exclude.²

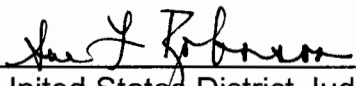
5. **Motion to strike the late instrumentalities.** On August 5, 2011, the court ordered Walker Digital to identify the instrumentalities for infringement to focus discovery. On August 19, 2011, Walker Digital identified Bing Maps and Streetside and further provided Microsoft with formal infringement contentions on December 2, 2011.

6. On September 25, 2012, during his deposition, a Microsoft engineer mentioned that Microsoft used Google Maps for competitive analysis. Walker Digital informed Microsoft (via email on October 12, 2012) that it intended to allege infringement based on Microsoft's internal use of Google Maps. Another engineer, on October 18, 2012, testified about an "Internal System" developed and used by Microsoft. Walker Digital then alleged these two additional instrumentalities against Microsoft and provided discussion regarding these in its expert report dated November 12, 2012.

²Walker Digital may identify this issue as a topic for discussion at the pretrial conference if Google appears to be presenting as trial evidence documents and/or testimony beyond the scope discussed above.

7. Given that Microsoft did not disclose these instrumentalities until the close of fact discovery, it is not surprising that these instrumentalities were not vetted by Microsoft and Walker Digital through the fact discovery process. However, upon learning about the “Internal System” (which was based on a publically available 2009 paper and 2010 patent application),³ Walker Digital chose to present its infringement allegations in a conclusory fashion in its expert report and did not provide an infringement chart. (D.I. 311, ex. 6 at ¶¶128-134) At this late stage, it is unreasonable for Microsoft to respond to conclusory allegations, with information that was not vetted through the discovery process. Further, as to Microsoft’s internal use of Google Maps, Microsoft was not given the opportunity to participate in the discovery process related thereto. Therefore, Microsoft’s motion to strike is granted.

8. **Conclusion.** Based on the foregoing, the court denies without prejudice Walker Digital’s motion to exclude testimony regarding commercial success of the accused Google products and services (D.I. 300), and grants Microsoft’s motion to strike untimely infringement theories (D.I. 312).


United States District Judge

³See Billy Chen et al., *Integrated Videos and Maps for Driving Directions*, presented at the ACM UIST 2009 Conference in Canada on October 7, 2009; U.S. Patent Application 2010/0235078 A1. (D.I. 313 at 1 & n.1; D.I. 311, ex. 8; D.I. 359, ex. 1)

EXHIBIT C

From: [Lee, Yoonjin](#)
To: [Sikora, Michael T.](#)
Cc: [Williamson, Amanda S.](#); [Dudash, Amy M.](#); [NS District Court](#); [Miller, Zachary D.](#); [jblumenfeld@morrisonichols.com](#); [Dellinger, Megan E.](#); [Raich, William](#); [Lipton, Alissa](#); [Flibbert, Michael](#); [Kim, Yoonhee](#); [Pehrson, Kaitlyn](#); [Lee, Eric](#); [O'Quinn, Ryan](#); [Kozikowski, John](#)
Subject: RE: Nippon Shinyaku Co. Ltd. v. Sarepta Therapeutics, Inc., No. 1:21-cv-01015-GBW (D. Del.)
Date: Friday, August 11, 2023 5:43:18 PM

Mike,

Following up on our meet and confer today, we will send you as a courtesy [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]. You should receive a separate email with a secure link to download those files.

We confirm that Sarepta's July 14th production was made based on a reasonable investigation, and that we did not locate [REDACTED]
[REDACTED]
[REDACTED]

We trust that this will resolve any purported concern that NS may have with respect to the production relating to the [REDACTED]

Regards,
Yoonjin

Yoonjin Lee, Ph.D.
Associate

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To: Lee, Yoonjin <Yoonjin.Lee@finnegan.com>; O'Quinn, Ryan <Ryan.O'Quinn@finnegan.com>
Cc: Williamson, Amanda S. <amanda.williamson@morganlewis.com>; NS District Court <NSDistrictCourt@morganlewis.com>; Miller, Zachary D. <zachary.miller@morganlewis.com>; jblumenfeld@morrisonichols.com; Dellinger, Megan E. <mdellinger@morrisonichols.com>; Raich, William <William.Raich@finnegan.com>; Lipton, Alissa <Alissa.Lipton@finnegan.com>; Flibbert, Michael <michael.flibbert@finnegan.com>; Kim, Yoonhee <Yoonhee.Kim@finnegan.com>; Pehrson, Kaitlyn <Kaitlyn.Pehrson@finnegan.com>; Lee, Eric <Eric.Lee@finnegan.com>; Sikora, Michael T. <michael.sikora@morganlewis.com>
Subject: RE: Nippon Shinyaku Co. Ltd. v. Sarepta Therapeutics, Inc., No. 1:21-cv-01015-GBW (D. Del.)

EXTERNAL Email:

Counsel –

Your self-serving statements below and efforts to rewrite the record fail to resolve our concerns re: the [REDACTED]. We thus do want to have a meet and confer. We are available at 10 ET/9 CT tomorrow. We can use the following dial-in/Teams info for our call:

Microsoft Teams meeting

Join on your computer, mobile app or room device

[Click here to join the meeting](#)

Meeting ID: 281 725 186 721

Passcode: 9UPP39

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Join with a video conferencing device

morganlewis@m.webex.com

Video Conference ID: 116 692 699 0

[Alternate VTC instructions](#)

Or call in (audio only)

[+1 267-428-0577,65636260#](tel:+1267428057765636260) United States, Philadelphia

Phone Conference ID: 656 362 60#

[Find a local number](#) | [Reset PIN](#)

Amy M. Dudash

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Assistant: Ethel Kump | +1.215.963.4810 | ethel.kump@morganlewis.com

From: Lee, Yoonjin <Yoonjin.Lee@finnegan.com>

Sent: Thursday, August 10, 2023 5:15 PM

To: Dudash, Amy M. <amy.dudash@morganlewis.com>; O'Quinn, Ryan <Ryan.O'Quinn@finnegan.com>

Cc: Williamson, Amanda S. <amanda.williamson@morganlewis.com>; NS District Court <NSDistrictCourt@morganlewis.com>; Miller, Zachary D. <zachary.miller@morganlewis.com>; jblumenfeld@morrisnichols.com; Dellinger, Megan E. <mdellinger@morrisnichols.com>; Raich, William <William.Raich@finnegan.com>; Lipton, Alissa <Alissa.Lipton@finnegan.com>; Flibbert, Michael <michael.flibbert@finnegan.com>; Kim, Yoonhee <Yoonhee.Kim@finnegan.com>; Pehrson, Kaitlyn <Kaitlyn.Pehrson@finnegan.com>; Lee, Eric <Eric.Lee@finnegan.com>; Sikora, Michael T. <michael.sikora@morganlewis.com>

Subject: RE: Nippon Shinyaku Co. Ltd. v. Sarepta Therapeutics, Inc., No. 1:21-cv-01015-GBW (D. Del.)

[EXTERNAL EMAIL]

Amy,

It is still unclear to us what NS is specially seeking from Sarepta with respect to [REDACTED]. As NS is well aware, no patent related to [REDACTED] is asserted in this U.S. litigation. Still, Sarepta undertook searches and produced information relating to [REDACTED] as a compromise to resolve NS's unreasonable discovery demands. Sarepta has satisfied its obligation pursuant to the parties' June 21 agreement. NS's contrary allegations are unfounded as explained below, and we write further to correct NS's misrepresentations.

- **Dr. Schnell's deposition:** NS claims that "[I]t was clear from Dr. Schnell's deposition that Sarepta's production relating to [REDACTED] was woefully deficient." But NS never asked Dr. Schnell about the data reported in [REDACTED].
[REDACTED].
- [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
- NS continues seeking "lab notebooks or reports that show the experimental methodology and results . . . reported in [REDACTED]," referencing Dr. Schnell's testimony about [REDACTED]. Schnell Tr. 84:13-17. [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
- **Excerpted lab notebooks:** NS is also trying to have it both ways on purportedly "improperly excerpted" lab notebooks. In producing Mr. Watanabe's lab notebook pursuant to the parties' June 21 agreement, NS produced only a handful of pages from what appears to be a lab notebook with nearly 200 pages "without identifying why other portions of the lab notebook [was] withheld." See NS00091284 (Mr. Watanabe's lab notebook containing a cover page and pages 29-42 only). Similarly, Sarepta in good faith produced [REDACTED].
[REDACTED].
When NS's counsel directly asked Dr. Schnell why the produced version of his lab notebook

was excerpted, he explained: [REDACTED]
[REDACTED] and [REDACTED] Schnell Tr. 203:10-15. NS's allegation that those lab notebooks were "improperly" excerpted is unfounded and contrary to the record.

We trust that our response will resolve any purported concern that NS has regarding the production pursuant to the parties' June 21 agreement. But to the extent that NS still insists on having a meet and confer, we can be available between 9 AM and 12 PM ET on Friday (August 11). In that meet and confer, please explain with particularity what, if any, information NS seeks regarding [REDACTED]. Please also be prepared to disclose the detailed search efforts that NCNP and NS carried out in locating documents, e-mail, and laboratory notebooks reflecting the experiments conducted at NCNP reported in the Patents-in-Suit, and an explanation as to how these documents were lost or otherwise unavailable.

Regards,
Yoonjin

Yoonjin Lee, Ph.D.

Associate

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From: Dudash, Amy M. <amy.dudash@morganlewis.com>

Sent: Wednesday, August 9, 2023 9:34 AM

To: Lee, Yoonjin <Yoonjin.Lee@finnegan.com>; O'Quinn, Ryan <Ryan.O'Quinn@finnegan.com>

Cc: Williamson, Amanda S. <amanda.williamson@morganlewis.com>; NS District Court <NSDistrictCourt@morganlewis.com>; Miller, Zachary D. <zachary.miller@morganlewis.com>; jblumenfeld@morrisnichols.com; Dellinger, Megan E. <mdellinger@morrisnichols.com>; Raich, William <William.Raich@finnegan.com>; Lipton, Alissa <Alissa.Lipton@finnegan.com>; Flibbert, Michael <michael.flibbert@finnegan.com>; Kim, Yoonhee <Yoonhee.Kim@finnegan.com>; Pehrson, Kaitlyn <Kaitlyn.Pehrson@finnegan.com>; Lee, Eric <Eric.Lee@finnegan.com>; Sikora, Michael T. <michael.sikora@morganlewis.com>

Subject: RE: Nippon Shinyaku Co. Ltd. v. Sarepta Therapeutics, Inc., No. 1:21-cv-01015-GBW (D. Del.)

EXTERNAL Email:

Yoonjin –

We are disappointed at Sarepta's apparent refusal to engage in the meet and confer process required by the Court's and Special Master's rules.

It was clear from Dr. Schnell's deposition that Sarepta's production relating to [REDACTED] [REDACTED] was woefully deficient. Sarepta [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]. NS has repeatedly requested [REDACTED]
[REDACTED]. Despite agreeing to produce documents "providing context around those experiments (including identifying any others involved)," Sarepta has not produced, for example, any lab notebooks or reports that show the experimental methodology and results of the reports referenced and reported in [REDACTED]. [REDACTED]
[REDACTED]
[REDACTED]

and produced them without identifying why other portions of the lab notebooks were withheld.

Although Sarepta states in a conclusory fashion that it has conducted “more than a reasonable search at this point for this data and has produced all that it was able to locate,” we have concerns regarding the reasonableness of the search Sarepta undertook in light of the lack of data produced (including, *inter alia*, that which we have identified above). We can discuss this further during our meet and confer.

Please identify a time to meet and confer by no later than 12pm ET on Friday (8/11), or we will proceed with a letter request to the Special Master indicating that you are refusing to meet and confer in a continued effort to obstruct the discovery process in this case.

Thanks,
Amy

Amy M. Dudash

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amy.dudash@morganlewis.com | www.morganlewis.com

Assistant: Ethel Kump | +1.215.963.4810 | ethel.kump@morganlewis.com

From: Lee, Yoonjin <Yoonjin.Lee@finnegan.com>

Sent: Tuesday, August 8, 2023 6:18 PM

To: Dudash, Amy M. <amy.dudash@morganlewis.com>; O'Quinn, Ryan
<Ryan.O'Quinn@finnegan.com>

Cc: Williamson, Amanda S. <amanda.williamson@morganlewis.com>; NS District Court <NSDistrictCourt@morganlewis.com>; Miller, Zachary D. <zachary.miller@morganlewis.com>; jblumenfeld@morrisnichols.com; Dellinger, Megan E. <mdellinger@morrisnichols.com>; Raich, William <William.Raich@finnegan.com>; Lipton, Alissa <Alissa.Lipton@finnegan.com>; Flibbert, Michael <michael.flibbert@finnegan.com>; Kim, Yoonhee <Yoonhee.Kim@finnegan.com>; Pehrson,

Kaitlyn <Kaitlyn.Pehrson@finnegan.com>; Lee, Eric <Eric.Lee@finnegan.com>; Sikora, Michael T. <michael.sikora@morganlewis.com>

Subject: RE: Nippon Shinyaku Co. Ltd. v. Sarepta Therapeutics, Inc., No. 1:21-cv-01015-GBW (D. Del.)

[EXTERNAL EMAIL]

Amy,

Your email does not answer our question as what other data NS requires for a “sufficient” showing regarding [REDACTED] produced per the parties’ June 21 agreement. Until NS can articulate it further, we do not see any reason to meet and confer.

Regards,
Yoonjin

Yoonjin Lee, Ph.D.
Associate

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From: Dudash, Amy M. <amy.dudash@morganlewis.com>

Sent: Tuesday, August 8, 2023 10:54 AM

To: O'Quinn, Ryan <Ryan.O'Quinn@finnegan.com>

Cc: Williamson, Amanda S. <amanda.williamson@morganlewis.com>; NS District Court <NSDistrictCourt@morganlewis.com>; Lee, Yoonjin <Yoonjin.Lee@finnegan.com>; Miller, Zachary D. <zachary.miller@morganlewis.com>; jblumenfeld@morrishichols.com; Dellinger, Megan E. <mdellinger@morrishichols.com>; Raich, William <William.Raich@finnegan.com>; Lipton, Alissa <Alissa.Lipton@finnegan.com>; Flibbert, Michael <michael.flibbert@finnegan.com>; Kim, Yoonhee <Yoonhee.Kim@finnegan.com>; Pehrson, Kaitlyn <Kaitlyn.Pehrson@finnegan.com>; Lee, Eric <Eric.Lee@finnegan.com>; Sikora, Michael T. <michael.sikora@morganlewis.com>

Subject: RE: Nippon Shinyaku Co. Ltd. v. Sarepta Therapeutics, Inc., No. 1:21-cv-01015-GBW (D. Del.)

EXTERNAL Email:

Ryan –

We can agree to your proposal for ex-US units, and have removed what previously was Issue #1. As for Issue #2, if Sarepta is willing to agree to, in the event an explanatory document doesn't already exist, provide a description of the rows in the ASP reports, we would be willing to drop Topic No. 56 from that issue.

Otherwise, we understand the parties to be at an impasse on these issues. Please confirm Sarepta

has no edits to the attached letter submission to the Special Master, **which, absent hearing of any edits, we intend to email to the Special Master by 5pm ET today.**

Please also provide your team's availability for a meet-and-confer on the Sazani / Kole data on Wednesday of this week.

Regarding Issue #8, we can confirm we understand all copies to be destroyed by Morgan Lewis and our vendors. The one open item is how you want to substitute Wong Exhibit 11. We have deleted this from our files, but recommend that Sarepta provide us and the court reporter a redacted version to substitute for the record copy, so that the record copy retains the exhibit sticker.

Amy M. Dudash

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Assistant: Ethel Kump | +1.215.963.4810 | ethel.kump@morganlewis.com

From: O'Quinn, Ryan <Ryan.O'Quinn@finnegan.com>

Sent: Monday, August 7, 2023 9:48 AM

To: Sikora, Michael T. <michael.sikora@morganlewis.com>

Cc: Williamson, Amanda S. <amanda.williamson@morganlewis.com>; Dudash, Amy M. <amy.dudash@morganlewis.com>; NS District Court <NSDistrictCourt@morganlewis.com>; Lee, Yoonjin <Yoonjin.Lee@finnegan.com>; Miller, Zachary D. <zachary.miller@morganlewis.com>; jblumenfeld@morrisnichols.com; Dellinger, Megan E. <mdellinger@morrisnichols.com>; Raich, William <William.Raich@finnegan.com>; Lipton, Alissa <Alissa.Lipton@finnegan.com>; Flibbert, Michael <michael.flibbert@finnegan.com>; Kim, Yoonhee <Yoonhee.Kim@finnegan.com>; Pehrson, Kaitlyn <Kaitlyn.Pehrson@finnegan.com>; Lee, Eric <Eric.Lee@finnegan.com>

Subject: RE: Nippon Shinyaku Co. Ltd. v. Sarepta Therapeutics, Inc., No. 1:21-cv-01015-GBW (D. Del.)

[EXTERNAL EMAIL]

Mike,

After a reasonable search, Sarepta is willing to produce the following information as part of a

[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

This is equivalent to NS's production [REDACTED].
[REDACTED].
See NS00091313. Indeed, Sarepta's core financial documents are more complete and more detailed than NS's, as depositions have confirmed. Mr. Wong confirmed that [REDACTED], while Mr. Gendron testified that [REDACTED]. See Wong Dep. Tr. at 192:16-193:22, 214:2-217:17; Gendron Dep. Tr. at 109:7-110:2. [REDACTED]
[REDACTED]. If NS agrees, please confirm that Issue #1 can be removed in its entirety from the letter to the Special Master.

For Issue #2, Sarepta is still investigating [REDACTED]. Our current understanding is that if found, these documents will speak for themselves and no testimony, oral or written, will be necessary. We hope to have an update by the middle of the week.

We have already addressed Issue #8 through our prior correspondence. Please confirm when the vendor has deleted the documents, and follow up with them if necessary. Since the vendor presumably has no work product, this should be a fairly simple task.

For Issue #6, as we discussed at length during the July 21 meet and confer, Sarepta is entitled to discovery of NS's corporate knowledge and understanding of the CERI reports, as well as other related documents and communications. The CERI reports were produced during the fact discovery period, with NS as the custodian. NS cited these documents in their invalidity contentions. As such, whether and how NS plans to use these documents during the expert phase of the case is separate from the discovery that Sarepta must conduct during the fact discovery phase. Written discovery responses that simply reiterate attorney arguments relating to "context" do not address that need. Please advise us if NS is willing to reconsider its position. Otherwise, the parties remain at an impasse and Sarepta will proceed with Issue #6 before the Special Master.

As to [REDACTED], your email and Shon Lo's email from Wednesday both continue to misrepresent Sarepta's production and Dr. Schnell's testimony. Dr. Schnell testified generally that [REDACTED]
[REDACTED]. Sarepta has undertaken more than a reasonable search at this point for this data and has produced all that it was able to locate. [REDACTED]
[REDACTED]
[REDACTED] NS also did not bother to question Mr. Schnell about any of this data at his deposition, so it is curious that NS is now putting such weight on it.

We trust this resolves the issues, but we are available to further discuss if necessary. As for a meet and confer on [REDACTED], we will follow up after the Takeda deposition concludes.

With best regards,
Ryan

Ryan P. O'Quinn, Ph.D.

Partner

Finnegan, Henderson, Farabow, Garrett & Dunner, LLP

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From: Sikora, Michael T. <michael.sikora@morganlewis.com>

Sent: Friday, August 4, 2023 6:15 PM

To: Lee, Yoonjin <Yoonjin.Lee@finnegan.com>; Miller, Zachary D.

<zachary.miller@morganlewis.com>; jblumenfeld@morrisnichols.com; Dellinger, Megan E.

<mdellinger@morrisnichols.com>; Raich, William <William.Raich@finnegan.com>; Lipton, Alissa

<Alissa.Lipton@finnegan.com>; O'Quinn, Ryan <Ryan.O'Quinn@finnegan.com>; Flibbert, Michael

<michael.flibbert@finnegan.com>; Kim, Yoonhee <Yoonhee.Kim@finnegan.com>; Pehrson, Kaitlyn

<Kaitlyn.Pehrson@finnegan.com>; Lee, Eric <Eric.Lee@finnegan.com>

Cc: Williamson, Amanda S. <amanda.williamson@morganlewis.com>; Dudash, Amy M.

<amy.dudash@morganlewis.com>; NS District Court <NSDistrictCourt@morganlewis.com>

Subject: RE: Nippon Shinyaku Co. Ltd. v. Sarepta Therapeutics, Inc., No. 1:21-cv-01015-GBW (D. Del.)

EXTERNAL Email:

Counsel:

Could you please provide a time on Monday for us to meet and confer regarding Sarepta's production of [REDACTED]?

Additionally, please advise on the status of the remaining issues so that we may also finalize the dispute letter to the Special Master.

Best,

Mike

Michael T. Sikora

Morgan, Lewis & Bockius LLP

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Celebrating 150 years of Morgan Lewis



From: Sikora, Michael T.

Sent: Tuesday, August 1, 2023 8:00 AM

To: 'Lee, Yoonjin' <Yoonjin.Lee@finnegan.com>; Miller, Zachary D.

<zachary.miller@morganlewis.com>; jblumenfeld@morrisnichols.com; Dellinger, Megan E.

<mdellinger@morrisnichols.com>; Raich, William <William.Raich@finnegan.com>; Lipton, Alissa

<Alissa.Lipton@finnegan.com>; O'Quinn, Ryan <Ryan.O'Quinn@finnegan.com>; Flibbert, Michael

<michael.flibbert@finnegan.com>; Kim, Yoonhee <Yoonhee.Kim@finnegan.com>; Pehrson, Kaitlyn

<Kaitlyn.Pehrson@finnegan.com>; Lee, Eric <Eric.Lee@finnegan.com>

Cc: Williamson, Amanda S. <amanda.williamson@morganlewis.com>; Dudash, Amy M.

<amy.dudash@morganlewis.com>; NS District Court <NSDistrictCourt@morganlewis.com>

Subject: RE: Nippon Shinyaku Co. Ltd. v. Sarepta Therapeutics, Inc., No. 1:21-cv-01015-GBW (D. Del.)

Yoonjin,

Please attached for our edits to the proposed letter to the special master. There are a few points we wish to clarify before submitting:

For issue (#1), you state a purported disagreement that we are at an impasse regarding profit and cost information, but we understood from the meet-and-confer that Sarepta did not intend to provide any additional information for [REDACTED]

[REDACTED]. From Mr.

Wong's testimony, we understand that [REDACTED]

[REDACTED]. Could you please clarify if there is any [REDACTED]

[REDACTED] that Sarepta does agree to produce?

Also, regarding your proposal to [REDACTED]

[REDACTED]

[REDACTED] If so, then we may be able to reach agreement here.

For issue (#2), we indicated for Topic 56 that we would be willing to consider written 30(b)(6) testimony [REDACTED] in lieu of a live witness. Is Sarepta not amenable to that proposal?

For issue (#6), we can confirm that no "pre-screening efforts" were carried out at NS. As we have explained, the CERI reports reflect testing conducted in expectation of forthcoming expert testimony in this case, and Sarepta will have the opportunity to explore their experimental design in connection with expert discovery. Sarepta has offered no reason why our offer to provide a written discovery response confirming our representations regarding the context of the CERI reports would be insufficient here.

For issue (#8), as stated on the meet-and-confer, we confirm that we agree to destroy the prior versions of the production documents.

Regarding [REDACTED], we disagree with your characterization of Sarepta's production. For example, Sarepta's production did not show [REDACTED]
[REDACTED]. If Sarepta does not agree to produce additional documents [REDACTED], please provide your availability for a meet-and-confer.

Best,

Mike

Michael T. Sikora

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Celebrating 150 years of Morgan Lewis



From: Lee, Yoonjin <Yoonjin.Lee@finnegan.com>

Sent: Friday, July 28, 2023 2:45 PM

To: Miller, Zachary D. <zachary.miller@morganlewis.com>; jblumenfeld@morrisnichols.com; Dellinger, Megan E. <mdellinger@morrisnichols.com>; Raich, William <William.Raich@finnegan.com>; Lipton, Alissa <Alissa.Lipton@finnegan.com>; O'Quinn, Ryan <Ryan.O'Quinn@finnegan.com>; Flibbert, Michael <michael.flibbert@finnegan.com>; Kim, Yoonhee <Yoonhee.Kim@finnegan.com>; Pehrson, Kaitlyn <Kaitlyn.Pehrson@finnegan.com>; Lee, Eric <Eric.Lee@finnegan.com>

Cc: Williamson, Amanda S. <amanda.williamson@morganlewis.com>; Dudash, Amy M.

<amy.dudash@morganlewis.com>; NS District Court <NSDistrictCourt@morganlewis.com>

Subject: RE: Nippon Shinyaku Co. Ltd. v. Sarepta Therapeutics, Inc., No. 1:21-cv-01015-GBW (D. Del.)

[EXTERNAL EMAIL]

Counsel,

Sarepta's proposed edits to the letter to the Special Master are attached.

While Sarepta disagrees with NS's characterizations of events and of Sarepta's Noninfringement Contentions, Sarepta will not oppose NS's motion to seek leave to serve its Amended Infringement Contentions. In our view, NS's Amended Contentions are still deficient both factually and legally for at least the reasons articulated in our letter dated July 10, 2023 and Sarepta's Noninfringement Contentions served July 11, 2023. To the extent that NS's expert(s) adopts NS's flawed analysis under the doctrine of equivalents, Sarepta will respond accordingly, and reserves all possible rights,

including without limitation moving to strike or exclude that testimony.

Sarepta is still investigating what financial information is available for [REDACTED] after a reasonable search. As has been repeatedly stated, Sarepta [REDACTED] [REDACTED] *E.g.*, Wong Dep. Tr. 269:12-21. Accordingly, we disagree that the parties are at an impasse at least on issue 1(i) in your draft letter to the Special Master. Sarepta does not agree to [REDACTED] [REDACTED]. Please advise if this will resolve the dispute. NS has provided no information whatsoever related to [REDACTED] [REDACTED], and thus is not entitled to the disproportionate production it seeks.

To be clear, Sarepta will produce a supplemental profit and loss statement when NS provides a date certain for producing its “[REDACTED]” documents. There is no excuse for the delay in producing these documents, which Gardner Gendron confirmed at his deposition 17 days ago were [REDACTED] [REDACTED]. Gendron Dep. Tr. 47:16-20. These documents are responsive to multiple outstanding Sarepta requests for production and should have been produced months ago, and certainly by the end of fact discovery. If NS does not provide by close of business today for this production a date certain that is within the next seven days, Sarepta will add an additional dispute seeking to compel [REDACTED] and additional deposition testimony to accompany them at NS’s expense. Additionally and alternatively, Sarepta will reserve the right to strike any reliance by any NS expert on future revenues, costs, and profits relating to Viltepso.

Sarepta also disagrees with NS’s characterization of documents produced per the parties’ agreement regarding exon 53 testing data reached on June 21. As an initial matter, NS mischaracterizes Dr. Schnell’s testimony with respect to [REDACTED] [REDACTED]. Dr. Schnell testified to [REDACTED] [REDACTED] [REDACTED]. Regardless, Sarepta has produced documents sufficient to show [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]. In contrast, NS still has not produced the data underlying multiple figures in its asserted patents-in-suit, including at least Figure 1 and 4-8, and has arbitrarily refused to produce exon skipping data post-dating 2013.

Regards,
Yoonjin

Yoonjin Lee, Ph.D.
Associate

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From: Lee, Yoonjin

Sent: Thursday, July 27, 2023 3:59 PM

To: Miller, Zachary D. <zachary.miller@morganlewis.com>; jblumenfeld@morrisnichols.com; Dellinger, Megan E. <mdellinger@morrisnichols.com>; Raich, William <William.Raich@finnegan.com>; Lipton, Alissa <Alissa.Lipton@finnegan.com>; O'Quinn, Ryan <Ryan.O'Quinn@finnegan.com>; Flibbert, Michael <michael.flibbert@finnegan.com>; Kim, Yoonhee <Yoonhee.Kim@finnegan.com>; Pehrson, Kaitlyn <Kaitlyn.Pehrson@finnegan.com>; Lee, Eric <Eric.Lee@finnegan.com>

Cc: Williamson, Amanda S. <amanda.williamson@morganlewis.com>; Dudash, Amy M. <amy.dudash@morganlewis.com>; NS District Court <NSDistrictCourt@morganlewis.com>

Subject: RE: Nippon Shinyaku Co. Ltd. v. Sarepta Therapeutics, Inc., No. 1:21-cv-01015-GBW (D. Del.)

Counsel,

We are considering your motion to seek leave to file amended contentions, your draft letter to the Special Master, and the alleged issues raised in your e-mail. We will provide our responses, including the identification of additional issues at impasse for the Special Master (including without limitation discovery surrounding NS's exon 53 skipping studies, discovery surrounding NS's various declarations, and discovery surrounding NS's first awareness of Popplewell), in due course.

Regards,
Yoonjin

Yoonjin Lee, Ph.D.

Associate

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Sent: Thursday, July 27, 2023 11:25 AM

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Cc: Williamson, Amanda S. <amanda.williamson@morganlewis.com>; Dudash, Amy M. <amy.dudash@morganlewis.com>; NS District Court <NSDistrictCourt@morganlewis.com>

Subject: Nippon Shinyaku Co. Ltd. v. Sarepta Therapeutics, Inc., No. 1:21-cv-01015-GBW (D. Del.)

EXTERNAL Email:

Counsel,

Nippon Shinyaku intends to seek leave with the special master to serve Amended Final Infringement Contentions. The Amended Contentions include updates only to the analysis with respect to steps e) and f) of claims 1 and 6 of the '322 Patent. A clean version of the proposed Amended Contentions, along with a version showing the changes (note that the changes in the A-7 chart are shown by highlighting), will be sent shortly via FTP due to email size limitations. The amendment is timely and warranted because, since the service of Nippon Shinyaku's original Final Infringement Contentions on June 22, 2023, at least the following events have impacted Nippon Shinyaku's contentions:

- The Court issued its claim construction Memorandum Opinion and Order on July 3, 2023 – specifically construing steps e) and f);
- Sarepta served Noninfringement Contentions on July 11, 2023 – identifying for the first time a contention that the application of the doctrine of equivalents would ensnare the prior art, an issue on which Sarepta bears the burden of production; and
- Nippon Shinyaku took the deposition of Dr. Jurjus Jurayj (Sarepta's 30(b)(6) witness on the manufacturing process relevant to steps e) and f)) on July 18, 2023, and received the final transcript on July 25, 2023.

Please let us know if Sarepta will oppose a motion for this limited amendment. In order to avoid any perceived prejudice, NS will not oppose any attempt by Sarepta to amend its Noninfringement Contentions solely to respond to NS's amendment, should Sarepta believe such amendment is needed. If Sarepta intends to oppose, we will include the proposed amendment as issue 6 in the attached draft letter to the special master.

Additionally, based on the meet-and-confer last week, we understand there to be at least five other issues regarding which the parties are at an impasse (noted in the attached draft letter to the special master). Could you please confirm (1) whether Sarepta has changed its position regarding any of these issues since the meet-and-confer; and (2) whether Sarepta agrees to provide [REDACTED] in supplementing its financial information?

Further, after having an opportunity to review the recently-produced documents reflecting experimentation underlying [REDACTED], it is clear that Sarepta has not produced documents sufficient to show [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] See, e.g., U.S. 2010/0130591 A1 at [0293]. [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Again, neither the application nor Sarepta's production appears to show this experimentation. Please confirm that

Sarepta will resolve this deficiency [REDACTED]
[REDACTED].

We also expect there will be certain information from Mr. Zenkus's and Dr. Schnell's depositions we will need clarity on [REDACTED]
[REDACTED], but our review of their transcripts remains ongoing. We will follow-up on those in due course.

Last, we wanted to follow-up to confirm that NS agrees to provide [REDACTED]
[REDACTED], and we are collecting those as expeditiously as possible. However, those documents likely will not be produced this week.

If Sarepta believes a meet-and-confer on these issues would be fruitful, we have some availability this afternoon.

Thanks,

Zach

Zachary D. Miller

Morgan, Lewis & Bockius LLP

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Celebrating 150 years of Morgan Lewis



From: Sikora, Michael T. <michael.sikora@morganlewis.com>

Sent: Friday, July 21, 2023 9:18 AM

To: Lee, Yoonjin <Yoonjin.Lee@finnegan.com>

Cc: Doukas, Maria E. <maria.doukas@morganlewis.com>; Williamson, Amanda S. <amanda.williamson@morganlewis.com>; Dudash, Amy M. <amy.dudash@morganlewis.com>; Betti, Ph.D., Christopher J. <christopher.betti@morganlewis.com>; Venegas, Ph.D., Krista Vink <krista.venegas@morganlewis.com>; Kraeutler, Eric <eric.kraeutler@morganlewis.com>; Morishita, Jitsuro <jitsuro.morishita@morganlewis.com>; Miller, Zachary D. <zachary.miller@morganlewis.com>; Hache, Ph.D., Guylaine <guylaine.hache@morganlewis.com>; NS District Court <NSDistrictCourt@morganlewis.com>; Lo, Shon <shon.lo@morganlewis.com>; Doi, Elsa <elsa.doi@morganlewis.com>; jblumenfeld@morrisnichols.com; mdellinger@mnat.com; Raich, William <William.Raich@finnegan.com>; Lipton, Alissa <Alissa.Lipton@finnegan.com>; O'Quinn, Ryan <Ryan.O'Quinn@finnegan.com>; Flibbert, Michael <michael.flibbert@finnegan.com>; Kim, Yoonhee <Yoonhee.Kim@finnegan.com>; Pehrson, Kaitlyn <Kaitlyn.Pehrson@finnegan.com>; Lee,

Eric <Eric.Lee@finnegan.com>

Subject: RE: Nippon Shinyaku Co. Ltd. v. Sarepta Therapeutics, Inc., No. 1:21-cv-01015-GBW (D. Del.)
– Letter

Yoonjin,

Sarepta's allegations of prejudice in relation to the CERI reports are unfounded. The CERI reports reflect testing conducted in expectation of forthcoming expert testimony in this case, and Sarepta will have the opportunity to explore their experimental design in connection with expert discovery.

As for each of your questions, we can confirm that Nippon Shinyaku would be the "sponsor" for the experimentation, that CERI is a contract research organization that independently performed the experimentation, and that the CERI reports produced describe the results from each antisense oligonucleotide that CERI was asked to test. In other words, there are no antisense oligonucleotides excluded from these reports, nor any other CERI reports for antisense oligonucleotides that Nippon Shinyaku is withholding. We likewise can confirm that none of the Nippon Shinyaku or NS Pharma witnesses deposed (or scheduled to be deposed) participated in performing the experimentation and/or their experimental design. If Sarepta would like this clarification to be formally adopted by Nippon Shinyaku in a discovery response, we can do so, but we do not agree to designate a witness.

We trust that this clarification that the CERI reports relate to forthcoming expert testimony resolves any purported concerns Sarepta may have had. That NS did not wait for expert discovery, but instead chose to produce the CERI Reports during fact discovery, in advance of final invalidity contentions, and shortly after the studies' completion (see, e.g., NS00102924 at 26 ("Study completion date.: May 17, 2023)) demonstrates that NS has acted in good faith and fully complied with its discovery obligations here.

Best,

Mike

Michael T. Sikora

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Celebrating 150 years of Morgan Lewis



From: Lee, Yoonjin <Yoonjin.Lee@finnegan.com>

Sent: Wednesday, July 19, 2023 6:50 PM

To: Sikora, Michael T. <michael.sikora@morganlewis.com>

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Subject: Nippon Shinyaku Co. Ltd. v. Sarepta Therapeutics, Inc., No. 1:21-cv-01015-GBW (D. Del.) – Letter

[EXTERNAL EMAIL]
Counsel,

Please see attached.

Regards,
Yoonjin

Yoonjin Lee, Ph.D.
Associate

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD.,)	
Plaintiff,)	
)	C.A. No. 21-1015 (JLH)
v.)	
)	DEMAND FOR JURY TRIAL
SAREPTA THERAPEUTICS, INC.,)	
Defendant.)	
<hr/>		
SAREPTA THERAPEUTICS, INC. and THE)	
UNIVERSITY OF WESTERN AUSTRALIA,)	
Defendant/Counter-Plaintiffs,)	
)	
v.)	
)	
NIPPON SHINYAKU CO., LTD. and NS)	
PHARMA, INC.,)	
Plaintiff/Counter Defendants.)	

**NIPPON SHINYAKU CO., LTD. AND NS PHARMA, INC.'S REPLY
IN SUPPORT OF THEIR MOTION *IN LIMINE* NO. 2 TO PRECLUDE
ARGUMENT OR EVIDENCE ON UNDISCLOSED FACTS**

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*Attorneys for Plaintiff/Counterclaim Defendant
Nippon Shinyaku Co., Ltd. and Counterclaim
Defendant NS Pharma, Inc.*

Dated: April 29, 2024

Sarepta's and UWA's suggestion that the evidence NS seeks to preclude "*ha[s]* been available" lacks credibility. *See* Opp. at 1. Their opposition tellingly provides *no* counter-citation to where they allegedly provided NS evidence on these discrete issues (A-D). And, as NS's motion demonstrates (with specific citations), NS *did* directly inquire regarding each issue with relevant fact witnesses and corporate designees. Mot. at 1-2. Sarepta and UWA either refused that discovery and/or plead ignorance, and the Court should hold them to those decisions now.

Sarepta and UWA also cast NS's motion as covering "broad categories of information." Opp. at 1. Not so. NS seeks to preclude them from offering new explanations regarding discrete issues that, during fact discovery, Sarepta and UWA claimed not to have. For example, both corporate designees claimed ignorance of the circumstances regarding Sarepta's licensing [REDACTED]. Ex. 8, Zenkus Dep. at 91:24-93:2 (testifying he is "not aware" of even how "Sarepta bec[a]me aware of the [REDACTED] from UWA"); Ex. 7, Shanahan Dep. at 34:22-35:2, 38:21-25. Likewise, when asked how Sarepta chose VYONDYS 53 (golodirsen), [REDACTED]. Sarepta should not be allowed to belatedly come forward with self-serving narratives on these issues, such as Sarepta sought out the [REDACTED] because it recognized the UWA Patent as covering an exon 53 "hot spot" or any information whatsoever regarding how it selected sequences for the blinded study.

Rule 403 and Rule 37(c) justify exclusion. NS's motion targets specific issues (A-D) it will have no fair opportunity to rebut should Sarepta and UWA offer new, *still-yet-to-be-disclosed* evidence at trial.

April 29, 2024

Respectfully submitted,

MORGAN, LEWIS & BOCKIUS LLP

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